Design of a Bio-realistic Surgical Phantom for Colorectal Surgical Training

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By

Shanna Bonanno

Mark Bright Bray

Parima Sharma

Isabelle Sillo

Phan Linh Dan Tran

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Dr. George Pins, Ph.D., Advisor
Department of Biomedical Engineering

Dr. Thomas Cataldo, M.D., Sponsor
Beth Israel Deaconess Medical Center

Abstract

Challenges in training surgical residents include restricted work hours, limited available cases for participation, and the absence of inanimate bio-realistic trainers that allow for practice without risking patients' health. A bio-realistic, inanimate trainer will offer a platform for recursive practice, and bridge the transition to the operating room. The goal of this project is to develop a bio-realistic, cost-effective, and reusable laparoscopic trainer for augmenting the learning curve for residents and allowing for repetitive practice and education. Initial findings suggest that our invention will accelerate the learning curve for residents and provide an affordable platform for training in low-income countries.

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Advisors
Dr. George Pins, Worcester Polytechnic Institute
Dr. Thomas Cataldo, Beth Israel Deaconess Medical Center

Other Contributors
Dr. Benjamin Allar, Beth Israel Deaconess Medical Center
Mitra Anand, Worcester Polytechnic Institute
Dr. Kevin Arndt, Beth Israel Deaconess Medical Center
Dr. Kristen Billiar, Worcester Polytechnic Institute
Dr. Ana Sofia Ore Carranza, Beth Israel Deaconess Medical Center
Dr. Gabrielle Cervoni, Beth Israel Deaconess Medical Center
Dr. Katherine Chen, Worcester Polytechnic Institute
Ms. Karen Coghlan, Worcester Polytechnic Institute
Dr. Martha Cyr, Worcester Polytechnic Institute
Dr. Jeremy Dressler, Beth Israel Deaconess Medical Center
Dr. Mia Dubosarsky, Worcester Polytechnic Institute
Dr. Anne Fabrizio, Beth Israel Deaconess Medical Center
Dr. Michelle Fakler, Beth Israel Deaconess Medical Center
Dr. Gregory Fischer, Worcester Polytechnic Institute
Dr. Melissa Fischer, UMass Memorial Healthcare
Dr. Matthew Flegal, Worcester Polytechnic Institute
Dr. Max Hazeltine, UMass Memorial Medical School
Dr. Arthur Heinricher, Worcester Polytechnic Institute
Mr. Robert Kirch, Worcester Polytechnic Institute
James Losille, Worcester Polytechnic Institute
Ms. Paula Moravek, Worcester Polytechnic Institute
Dr. Jonathan Pastrana del Valle, Beth Israel Deaconess Medical Center
Dr. Tomás Rodríguez, UMass Memorial Medical School
Dr. Claire Sokas, Beth Israel Deaconess Medical Center
Dr. Alessandra Storino, Beth Israel Deaconess Medical Center
Tyler Vu, Worcester Polytechnic Institute
Ms. Lisa Wall, Worcester Polytechnic Institute
Bryan Wind, Blood Farm Groton, MA
Dr. Daniel Wong, Beth Israel Deaconess Medical Center
Mr. Jorge Yarzebski Jr., UMass Memorial Medical School
Dr. Haichong Zhang, Worcester Polytechnic Institute

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1.0 Introduction

Across the nation and over the past several decades, there has been an increase in the number and complexity of surgical procedures; this is partly the result of improved surgical tools/techniques and the discovery of new drugs, but largely due to the increased medical needs of an aging U.S. population [1] [2] [3] [4]. In 2009, 48 million surgical inpatient procedures were performed in the United States [5]. Following historical trends, the surgeries tended to focus on specific body systems with cardiovascular surgeries accounting for 7.3 million surgeries, and digestive and musculoskeletal procedures accounting for 6.1 million and 5.2 million surgeries, respectively [5]. Despite surgeries becoming more commonplace [4], patients still find the prospect daunting [6].

A 2011 study from the Agency for Healthcare Research and Quality (AHRQ) indicated that in deciding to undergo surgical procedures, patients are increasingly reliant on information about provider competency and public reports of a procedure's quality measures [6]. Among the chief concerns of patients and their family members are "the likelihood of surgical success—i.e., the surgery achieving its intended outcome—and avoidance of complications" [6]. This sentiment is not unsubstantiated. In fact, a 2003 study examined the relationship between the number of surgeons in a hospital and operative mortality at a given hospital in the United States using national Medicare claims for 474,108 patients who underwent one of eight cardiovascular procedures or cancer resections. The study concluded that "[p]atients can often improve their chances of survival substantially, even at large hospitals, by selecting surgeons who perform the operations frequently" [7]. The results of a 2020 study of hospital volume and operative mortality supported these findings by concluding that survival rates improved for operations at high-volume hospitals, where surgeons presumably have more procedure-specific experience and thus better clinical judgement and technical skill for the surgery [7][8][9]. For hospital systems and surgeons, alleviating these concerns may be a matter of clinician volume and surgical expertise.

The path to becoming a surgeon and gaining surgical expertise in the United States is largely prescribed. After completing medical school, trainees enter a residency program in their chosen specialty for three to seven years and obtain national licensure and board certification to begin practicing [10]. Traditional surgical training employs the adage "See One, Do One, Teach One," meaning that residents would be expected to do a procedure after observing it the first time and would be able to teach another trainee how to do the procedure [11]. This practice has been criticized for putting patient safety at risk by having inexperienced, inadequately trained doctors perform medical procedures [11]. In response to patient concerns, residency programs have expanded to a more competency-based teaching model; the adage "See One, Do One, Teach One," has become "'see many, learn from the outcome, do many with supervision and learn from the outcome, and finally teach many with supervision and learn from the outcome'" [11].

Employing this competency-based teaching model has potential to improve the learning outcome for residents and increase their confidence in successfully performing surgical procedures when they get to the operating room. However, low-volume hospitals and hospitals in low-income countries may not have the resources necessary to employ this model. In addition, training in the operating room poses severe risk to patients' health. Therefore, new training models should be developed that allow residents to train without the need for high-volume infrastructures and without risking patients' health. Furthermore, technological advancements in surgery have led to a shift towards minimally invasive procedures, or laparoscopy, to decrease pain and the invasiveness of procedures [12]. However, there are no existing realistic models to support the training for laparoscopic techniques. Given these multiplex limitations, there is a significant need for an inanimate laparoscopic trainer that can augment the learning curve for residents and allow for repetitive practice as a recursive adjunct for human surgical training.

The aim of this project was to design and develop a bio-realistic, cost-effective, and reusable surgical trainer that recapitulates normal human tissue, and readily allows medical institutions to train their surgical residents. The model should be constructed from materials that accurately mimic the biomechanical properties of human abdominal organs. The phantom should equip residents with translatable skills needed to complete procedures in the operating room successfully, while also being light weight and easy to use. Finally, the model should maintain a low cost to increase accessibility of laparoscopic training tools, and therefore increase the number of laparoscopic trained surgeons across the world.

To achieve this aim, the team went through the engineering design process beginning with the identification of the stakeholder groups involved and affected by this project. Next, based on the information gathered from stakeholders and further research, the needs of the project were analyzed within the constraints and scope of the major qualifying project timeline. Once the needs were analyzed, based on the main objectives for the project, design functions and specifications were determined for each objective. Alternative designs were developed and ranked against the design objectives, functions, and specifications to determine which design was the best option to move forward with testing and fabrication. Next, mechanical testing on biological tissue (bovine), and synthetic materials was performed. Through comparative analysis of bovine tissue properties and human tissue properties found in literature, with synthetic material properties, materials were selected to fabricate the surgical phantom. To fabricate the surgical phantom, different molding techniques were employed based on the type of organ being fabricated. A box trainer was developed as a platform for using the surgical phantom with laparoscopic tools for training laparoscopic skills.

The development of the surgical phantom demonstrates that it is cost-effective and easy to use as a laparoscopic training model. Further work needs to be completed to fabricate the model with accurate human organ dimensions and with materials that are more bio-realistic. Further validation needs to be conducted to investigate how well the surgical phantom trains residents with translatable skills to the operating room. Future research and testing should be conducted to ensure the model is reusable as well. However, many of the residents that validated the surgical phantom mentioned that there is no surgical trainer like this one, and it is a trainer that they believe would aid in skills training outside of the operating room. These results show that this phantom with more research and development has the potential to be scaled up to a full abdominal model, providing training for any surgical procedure within the abdominal cavity. Results also show that this cost-effective surgical trainer has the ability to be marketed to low-income countries where access to appropriate training is limited.

The project was supported by Worcester Polytechnic Institute and sponsored by Beth Israel Deaconess Medical Center (BIDMC). The research was conducted in close collaboration with Dr. Thomas Cataldo (Assistant Professor of Surgery at Harvard Medical School). The following sections discuss the clinical and market need for a tool such as this phantom, training models that are currently used to train surgical residents, the project strategy, the design process, and the development of the surgical phantom.

2.0 Literature Review

2.1 Significance of Surgical Training

Surgical techniques are constantly progressing to meet the needs of healthcare. Technologies, such as laparoscopy and surgical robotics, have emerged to meet the desire for minimally invasive surgery, since the technique would reduce damage to the patient's body and decrease recovery time compared to traditional open surgery. The shift to minimally invasive surgical procedures reveals the need for comprehensive surgical training, as these techniques are new and require great precision. Repetitive training and practice outside of the operating room, using surgical models and simulators has been successful in many circumstances [13]. In a study conducted with general surgical residents at Yale University School of Medicine and the University of Toronto, it was found that 95.5% of participants felt that their laparoscopic skills improved from simulation training. Furthermore, 92.5% of participants stated that their learned skills were transferrable to the operating room [14]. The most preferred simulation device was the live animal model, followed by the cadaver. Virtual reality simulators were preferred the least out of all the simulation models available. 91% of residents expressed the desire for mandatory or designated time for simulation training in their resident training program [14].

In addition to the desire for more surgical training opportunities, studies have also confirmed the effectiveness of these training models. Constant and repetitive surgical practice has been found to enhance psychomotor skills, hand-eye coordination, and ambidextrous surgery during endoscopic and laparoscopic procedures [13]. Sixteen surgical residents in their postgraduate year at the Yale University School of Medicine Department of Surgery were studied to evaluate the effectiveness of virtual reality training. It was found that virtual reality training participants performed a gallbladder dissection 29% faster than those that only had traditional training comprised of standardized coursework and observation [13]. Virtual reality trainees were found to make five times less errors and were nine times more likely to proceed at a steady rate during the surgery [13]. The graph in Figure 1 demonstrates the significant decrease in mistakes made by virtual reality trained surgeons during the procedure.

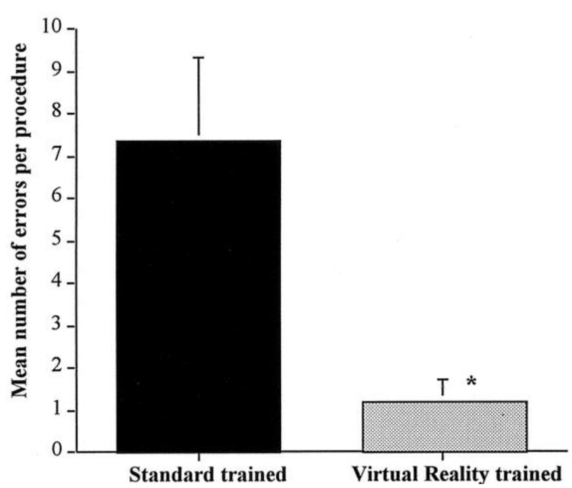

Figure 1: Average Number of Errors in a Procedure for Surgical Residents [15]

Further research also suggests that training programs that incorporate bio-realistic, hands-on training improve sensory perception and transferability of skills into the operating room. The ability to gradually increase complexity at a controlled pace reduces stress in the learning environment and allows students to learn from their mistakes [14]. These characteristics are hard to achieve with the traditional approach of having the trainee observe the mentor during operation (mentor training model). In a study conducted at the American College of Surgeons, accredited by Education Institute, 42 novice surgical trainees were trained to proficiency on laparoscopic suturing. In order to achieve proficiency, the trainees had to perform the technique with speed, smooth motion, and no errors [15]. The trainees' techniques were also evaluated using the Global Operative Assessment of Laparoscopic Skills. It was found that 71% of participants were trained to proficiency on the simulator while being able to apply these skills in the operating room [16]. Therefore, the "mistake friendly" environment of simulation training is beneficial to the preservation and transferability of surgical skills into the operating room.

Aside from improvement in skill retention and performance, surgical trainees, surgical teams, and patients also benefit from training models. The mentor-trainee model restricts residents to training only when patient contact is available. However, other training models allow more flexible and unlimited training time. Some training devices also offer at home courses, such as the Advanced Suturing six-week course using a traditional laparoscopic box trainer [17]. With the emphasis on reducing the number of hours surgeons work in Europe and the United States, the importance of practicing fine motor skills and new surgical techniques is even greater. This, coupled with rising student numbers, higher patient expectations, and decreased patient availability, requires a transition from the conventional mentor-trainee model to a more "hands-on" approach [14]. A study at the University of Tennessee Medical Center-Knoxville found that, out of 14,452 cases, the mentor-trainee model cost the hospital $53 million extra per year [18].

Amongst a group of attending surgeons at teaching hospitals in Massachusetts, 43% of surgical errors were due to failure in teamwork and communication [19]. 53% of incidents were due to lack of experience or competency [13]. In terms of patient benefits, a metanalysis of laparoscopic inguinal hernia repair procedures was shown to reduce intraoperative complications by 30% and postoperative complications by 27% when simulation of the surgery was implemented [20]. Operating time was also decreased by 6.5 minutes, which also contributed to better patient outcomes [13].

2.2 Importance of Anatomy and Physiology in Surgical Training

To allow for safe medical practices, the study of anatomy is imperative. Not only do doctors need to understand anatomy and translate that knowledge to the operating room, but they need to be able to effectively discuss anatomy with other medical professionals when preparing for and performing a patient case [21]. Furthermore, because there are many close-knit organs within the abdominal cavity, residents who specialize in colorectal surgery must become experts in human anatomy to avoid damaging nearby organs and successfully complete surgical operations. Having an in-depth understanding of the abdominal anatomy is crucial for diagnosing and treating the pathology within [22].

The human abdomen, also known as the abdominopelvic cavity, is the region between the thoracic diaphragm and the pelvic brim [22]. It is enclosed by the abdominal muscles at the anterior, and by the vertebrae at the posterior. The cavity consists of the digestive, urinary, endocrine, exocrine, and circulatory systems. The abdominopelvic cavity is subdivided into four quadrants by location: the right upper, right lower, left upper, and left lower regions. The abdominal division's purpose is to characterize regional anatomy and help surgeons determine the site of disease based on which quadrants experience pain.

Due to time and financial constraints, the scope of this project will focus on the right upper quadrant (RUQ). In colorectal surgery, the RUQ is clinically significant for two main reasons. The first reason is that the transverse colon is partially located in this region and is a site of interest for colorectal surgeries, such as in a right colectomy. The second reason for focusing on the RUQ is due to the number of organs within this region that must not be damaged during surgery. Since the RUQ houses organ sites for colorectal surgeries, as well as important organs that should not be damaged, this quadrant is important to investigate. Figure 2 represents the four quadrants, with the RUQ highlighted. The following organs are located within the RUQ and will be defined in sections 2.2.1-2.2.8: transverse colon (partially), small intestine/duodenum (partially), mesentery, stomach (partially), liver, gallbladder, right kidney, and peritoneum.

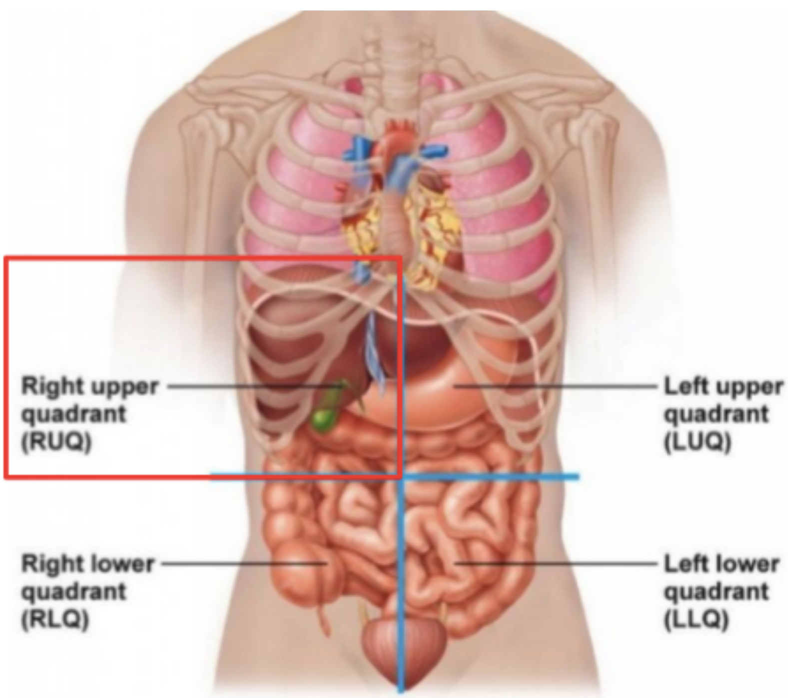

Figure 2: Image of the Abdomen [23]

2.2.1 The Transverse Colon

The colon, as shown in Figure 3, also known as the large intestine, is an organ that is divided into four different sections: ascending, transverse, descending, and sigmoid colon [24]. The transverse colon is the section that is anterior to the duodenum and runs across the upper abdomen [24]. The transverse colon is 45 cm in length, and the diameter is roughly 7 cm [25]. Additionally, the colon appears segmented because of certain structures called haustra [26]. The function of the colon is to aid in chemical digestion, to absorb water and electrolytes, and to transport the feces to the rectum [26]. Chyme, liquid waste, enters the colon from the small intestine. The colon then absorbs water and any additional nutrients from the chyme as it moves due to peristaltic motion [27]. The remaining chyme is turned into solid feces and transported down to the rectum. According to an experiment performed at the University of Edinburgh, the burst strength and tensile strength of the transverse colon were measured to be 1223 ± 701 g and 98 ± 57 g/mm^2, respectively [28].

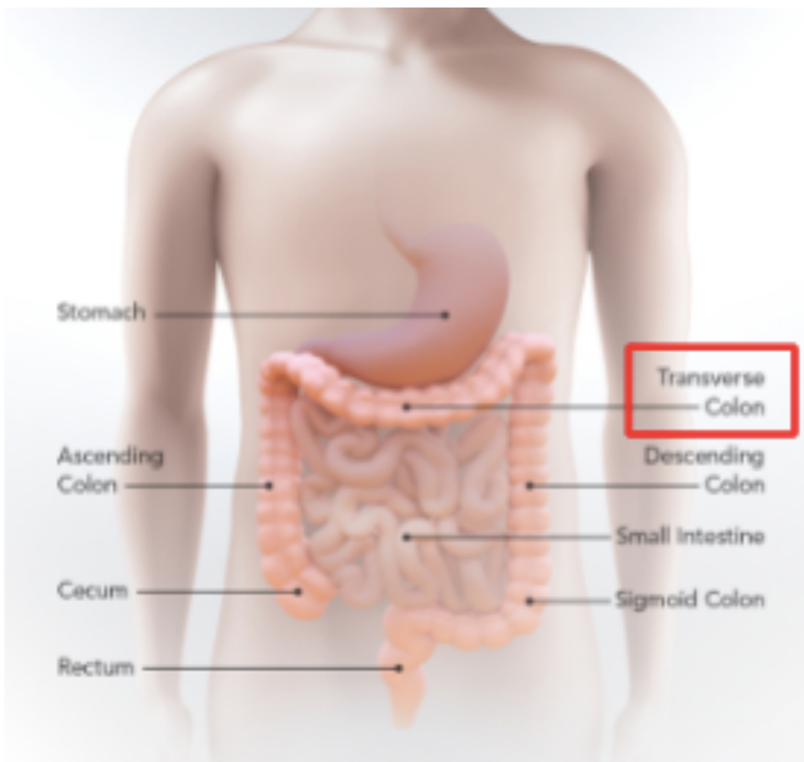

Figure 3: Image of the Colon [29]

2.2.2 The Small Intestine and Duodenum

The small intestine, as shown in Figure 4, is an organ in the gastrointestinal (GI) tract that is responsible for most of the nutrient and mineral absorption in the body [30]. In addition, the organ also provides immunological barriers, endocrine secretion, and maintains a water-electrolyte balance. It is 7 m long and 3 cm wide, making it the longest organ in the GI tract [30].

There are three sections in the small intestine: the duodenum, jejunum, and ileum. The duodenum is approximately 25 cm in length and is the first section of the small intestine. It is responsible for the breakdown of food using enzymes and other secretions like bile. The average length of both the jejunum and ileum is 5 m, where the jejunum is 2 m long and the ileum is 3 m long [30]. These sections are attached to the posterior abdominal wall by the mesentery tissue. Their function is to absorb sugars, amino acids, fatty acids, and other nutrients [30]. The tensile properties of the small intestine are reported to be 0.9 MPa for maximal stress and 140% for destructive strain [31].

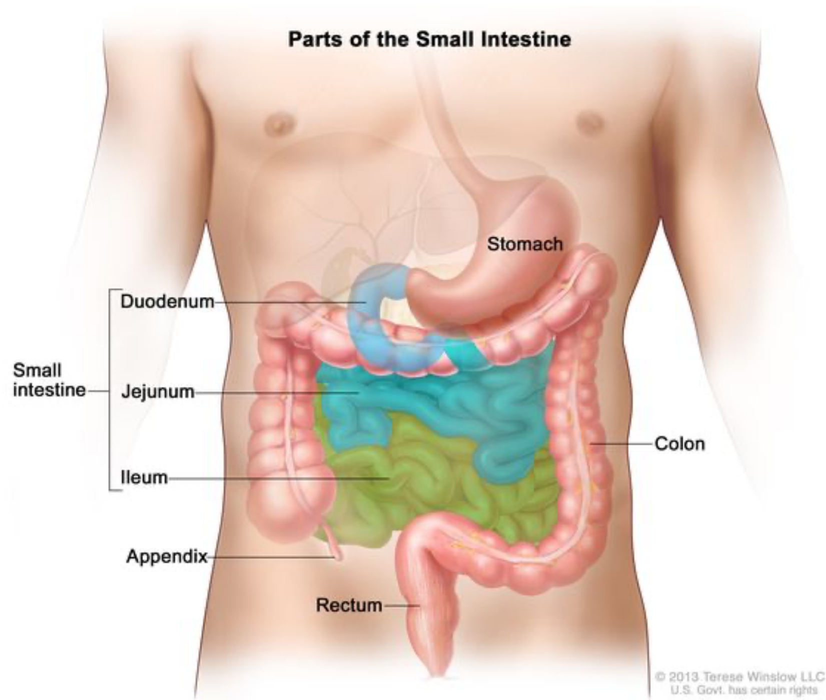

Figure 4: Image of the Small Intestine [32]

2.2.3 The Mesentery

The mesentery, as shown in Figure 5, is a mesodermal, fan-shaped organ made by folding the peritoneum into two layers [33]. Its component parts include mesentery proper, transverse mesocolon, sigmoid mesocolon, and mesoappendix [33]. The tissue extends from the posterior abdominal wall to the small and large intestines, and its dimensions are 15 cm long and 20 cm wide [34]. The mesentery helps to anchor the small and large intestines and reduce their friction, which permits some movement of these organs [35]. Additionally, the mesentery stores fat and provides a passage for blood vessels, nerves, and lymphatic vessels to nourish the intestines. Studies have been performed to determine the mechanical properties of mesentery tissue in model organisms, such as pigs. An experiment completed at the University of Limerick, in Ireland, found that the mesocolon and small intestinal mesentery had tissue strengths of 3.552 ± 0.803 MPa and 1.595 ± 0.461 MPa, respectively [36].

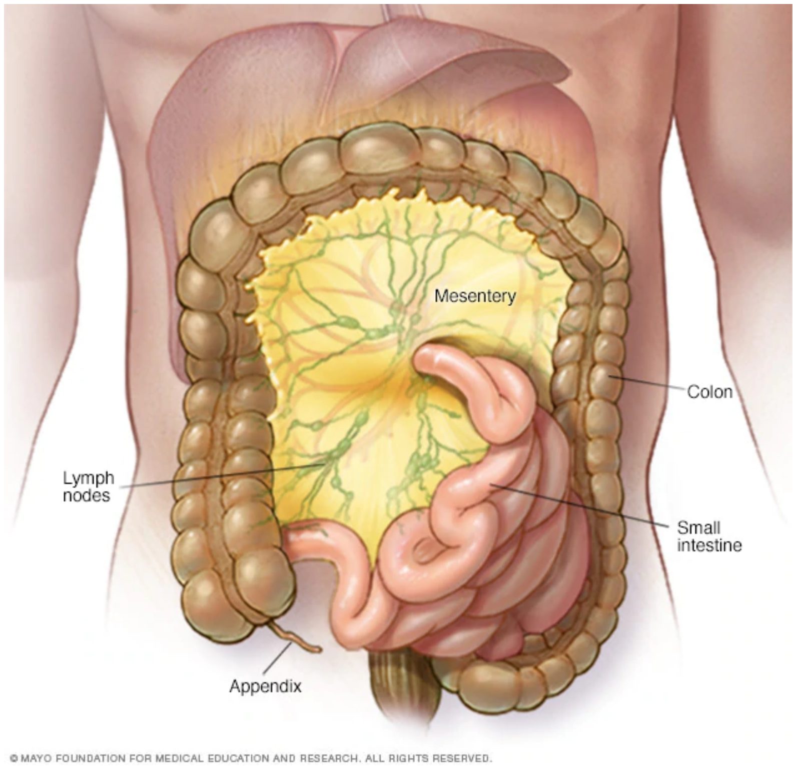

Figure 5: Image of the Mesentery [37]

2.2.4 The Stomach

The stomach, as shown in Figure 6, is a muscular sac that lies beneath the diaphragm and between the end of the esophagus and the duodenum [38]. It is divided into three regions: fundus, body, and antral; although, there are no physical distinctions between these parts. The stomach is the most dilated part of the digestive tract. Its capacity varies significantly, approximately 45 mL when empty and up to 1000 –1500 mL when full [38], [39]. The stomach is anchored to surrounding organs by ligamentous attachments, and its wall thickness normally ranges from 2-5 mm [39]. Its primary function is to store and mix food with digestive chemicals, such as acid, mucus, and pepsin. This mixture is then slowly released into the small intestine at a controlled rate for nutrient absorption. According to a study conducted by Volynskaya Hospital in 2002, the maximal stress and destructive strain of the stomach are 0.7 MPa and 190% for axial specimens, and 0.5 MPa and 190% for transversal specimens [31].

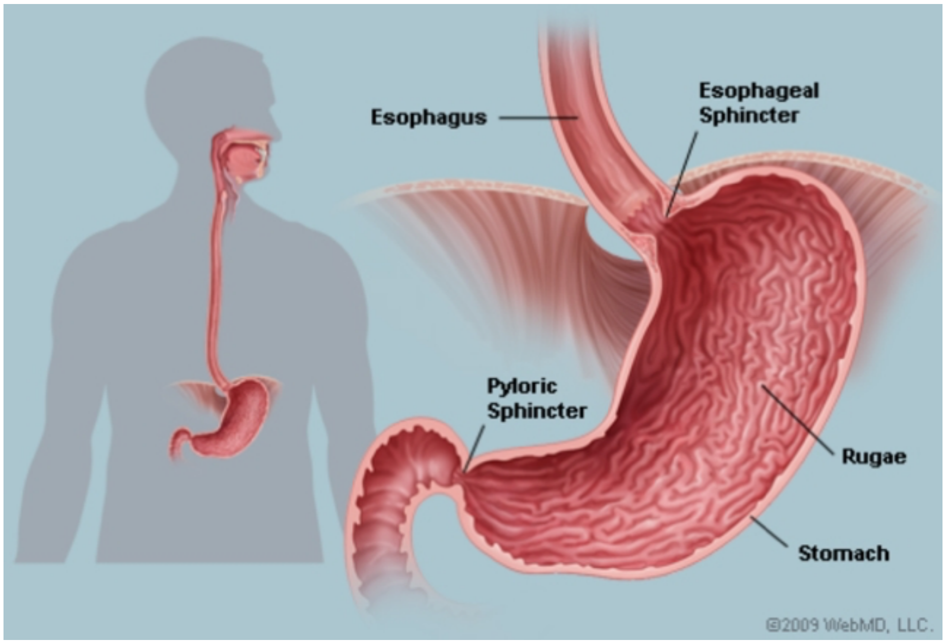

Figure 6: Image of the Stomach [40]

2.2.5 The Liver

The liver, which can be seen in Figure 7, is an important organ that helps to regulate metabolite levels in the blood. As blood passes through the liver, nutrients are broken down and metabolized, so it can be more easily processed by the other organs in the digestive tract. Additionally, it releases a substance called bile for storage in the gallbladder. Bile assists in the breakdown of lipids and removal of waste [41]. Other functions of the liver include producing cholesterol, storing glucose in the form of glycogen, making proteins that transport fat, and metabolizing drugs [41]. The average liver size for a male is about 10.5 cm [42].

2.2.6 The Gallbladder

The gallbladder, as shown in Figure 7, is a hollow organ located behind the liver, and it is around 7-10 cm long and 5 cm wide [43]. This organ is surrounded by the visceral peritoneum, and its most important function is to store a substance called bile that is produced in the liver. Specifically, the gallbladder holds between 30 and 80 mL of bile [43]. Bile is a dark green substance, composed of water, salts, cholesterol, and fats, that is primarily used for facilitating fat digestion [43]. The bile is released into the duodenum via the common bile duct when the muscular walls of the gallbladder contract [43]. After release, the salts in the bile help break down and absorb fat droplets. Additionally, the mechanical properties of the gallbladder have been documented in research: the axial elastic modulus is 641.20 ± 28.12 kPa, and the transversal elastic modulus is 255 ± 24.55 kPa [44].

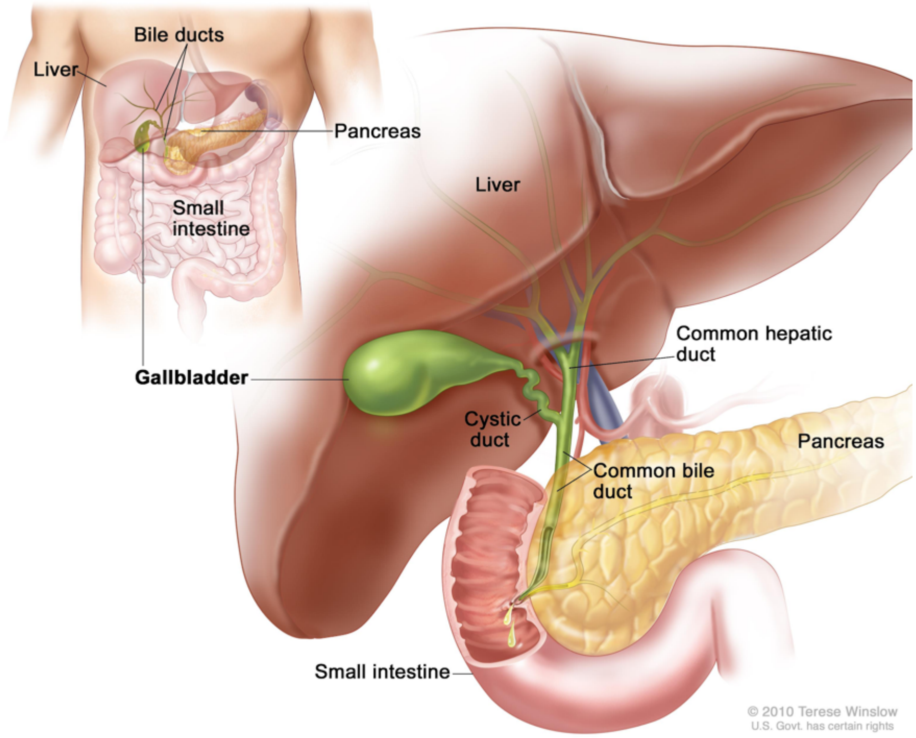

Figure 7: Image of Liver and Gallbladder [45]

2.2.7 The Right Kidney

The kidneys, as shown in Figure 8, are responsible for maintaining a stable environment in tissues by filtering waste from blood [46]. A kidney on average has approximately 1.2 million nephrons, which are the kidney's functional unit. The nephron works to remove waste and excess water from the blood. It consists of the Bowman's capsule, glomerular capillary tuft, proximal convoluted tubule, loop of Henle, and distal convoluted tubules. All these parts are important for urine formation [46]. A study conducted by Innsbruck Medical University reported that the right kidney pole to pole length (LLP) is 108.5 ± 12.2 mm and the left kidney LLP is 111.3 ± 12.6 mm [47]. The data were collected from 2,068 kidneys in 1,040 adults. It is important to note that many factors, such as BMI, height, gender, or age may impact kidney size [47]. Research in 2017 investigated the mechanical properties of the kidney using 20 cadavers [47] Results of the study showed that the axial elastic modulus and failure stress are 180.32 and 24.46 kPa, and the transversal elastic modulus and failure stress are 180.32 and 24.46 kPa respectively [48].

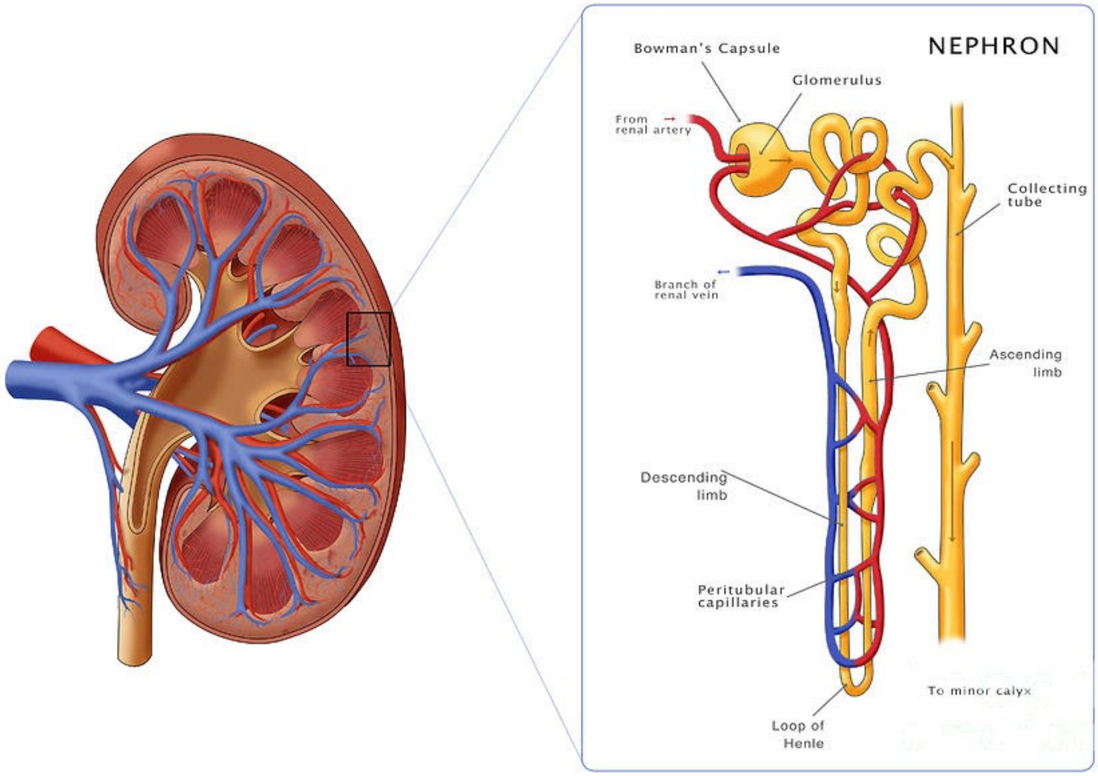

Figure 8: Image of the Kidney [49]

2.2.8 The Peritoneum

The peritoneum, as shown in Figure 9, is a continuous membrane forming the abdominal cavity lining. It supports and serves as a conduit for blood vessels, lymphatic vessels, and nerves. The peritoneal lining is composed of the superficial parietal layer and the deep visceral layer. There is a potential space between the two layers that contain 50 to 100 mL of serous fluid that acting as a lubricant to prevent friction between the peritoneum and abdominal organs. The parietal peritoneum, connecting to the abdominal and pelvic walls, is the outer layer. Inside the intraperitoneal vacuum, the inner visceral layer wraps around the internal organs. The retroperitoneal organs include the aorta, esophagus, parts of the duodenum (second and third sections) and colon (ascending and descending), pancreas, kidneys, ureters, and adrenal glands. The intraperitoneal organs include the stomach, spleen, liver, parts of the duodenum (first and fourth sections) and colon (transverse and sigmoid) [50].

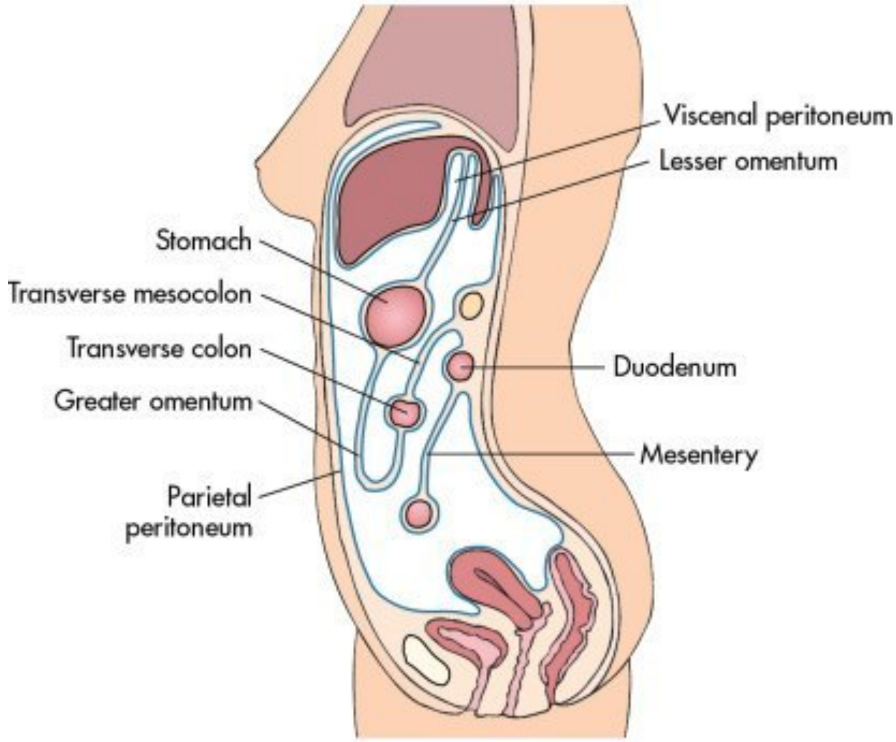

Figure 9. Image of the Peritoneum [51]

2.3 Colorectal Surgery

Colorectal surgeons perform surgeries within the abdominopelvic region and interact with the organs in the RUQ in many patient cases. Colorectal surgery is an area of medicine that specifically deals with the rectum, anus, and colon. Because the abdominopelvic cavity is complex and has many different organs within, it is important to have a good understanding of the surgical site. Detailed and repetitive training is important to reduce mistakes made in the operating room. Therefore, there is a need for surgical training models outside of the operating room. With advancements in technology, surgical training models must also adapt to meet the skill training necessary for performing new techniques.

2.3.1 Technological Advancements in Colorectal Surgeries

The traditional way to operate on patients has always been open surgery. However, recent advancements in technology are providing better, cheaper, and safer options for surgery, such as laparoscopy and robotic-assisted surgeries. One specific surgical area that has been utilizing laparoscopy and robotic-assisted surgeries is colorectal surgeries, which includes procedures like colectomies or removal of the colon.

The colon is part of the digestive system and is more commonly referred to as the large intestine. There are two types of colectomy procedures: partial colectomy and total colectomy [52]. In partial colectomy, part of the colon is removed, whereas in total colectomy, the entire colon is removed. In open surgeries, one large incision is made in the area that is being operated on, making such surgeries highly invasive. During an open colectomy surgery, a big incision is made in the abdominal area. The surgeon then must work through all the fat tissue and blood vessels before reaching the colon. Once at the colon, the surgeon will remove the appropriate part, and the incision will be closed [52]. There are many possible complications with open surgeries including hernia, damage to nearby structures, bleeding, or infections [52]. There are some procedures put in place to prevent infections, which include wearing protective equipment during the operation and covering the incision.

French surgeon Dr. Phillip Mouret completed the first video-laparoscopic cholecystectomy, surgical removal of the gallbladder [53]. Initially, there was skepticism in the medical community about this new approach; however, the approach quickly became widely accepted and is now a common method to perform minimally invasive surgeries. In laparoscopic surgery, multiple small incisions (around 1.0 to 1.5 cm) are made near the umbilicus in the abdominal area [54]. The laparoscope is approximately 30 cm long, and the tip is inserted into one of these incisions [55]. The surgical instruments used for operating are then inserted through the other incisions. The abdomen is first filled with carbon dioxide gas, which helps the surgeon to see the organs and have more space while operating [54]. During the operation, the camera (up to 16x magnification) on the laparoscope will project the interior view of the abdomen onto a 2D screen [55]. For a colectomy, one incision will be slightly bigger to allow for the removal of the colon. Laparoscopic techniques reduce infection, pain, and recovery time as a result of these smaller incisions [56]. This type of surgery allows for less direct contact with the human tissue.

According to the *Robotic colorectal surgery for laparoscopic surgeons with limited experience* article, "performance of the operation within the body cavity avoids the cooling, drying, excessive handling and retraction of internal organs associated with convention 'open' techniques" [57]. Additionally, less analgesia is required so patients have less side effects. However, there are some limitations with laparoscopic surgery. For example, the 2D view of the organs is limited, the surgical instruments could have restricted motion, and some of the surgeon's hand positions may not feel natural [57].

Recently, a new type of laparoscopy involving the assistance of robots is becoming more popular. One of these robotic systems is the Da Vinci® robot, which was created by the Intuitive Surgical company in California. The United States Food and Drug Administration (FDA) approved the Da Vinci® surgical system for use in 2000 [53]. Furthermore, the first robotic colon surgery was performed in 2002 [53]. In this type of surgery, the surgeon controls robotic arms that operate directly on the patient. The camera and robotic arms go through small abdominal incisions, like traditional laparoscopic procedures, as seen in Figure 10 [57]. The camera provides a high definition, 3D view of the internal organs, which increases the surgeons' depth perceptions.

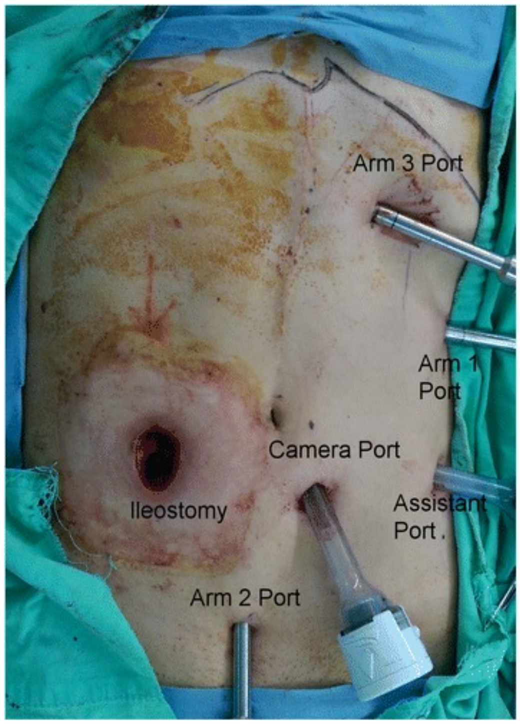

Figure 10: Different Ports for a Robotic Right Hemicolectomy [57]

The Da Vinci® robot allows "the surgeon to perform with enhanced dexterity, precision, vision, and control" [57]. The robot especially gives more control to surgeons who normally might have tremors while operating. Additionally, the robotic arms offer a greater range of movement, permitting the surgeon to operate in more natural positions. Overall, robotic-assisted laparoscopy helps to further increase precision and lower surgical complication [57].

2.3.2 The Clinical Need

Laparoscopic surgery was first investigated in 1911 [58]. Since then, laparoscopy has been investigated in many fields of surgery. Research has shown that laparoscopic colorectal surgery in particular has advantages over traditional surgeries. These advantages include reduced postoperative pain, earlier recovery of bowel function, and shorter hospital stay [12]. However, due to the finer technicalities of laparoscopic surgery, the learning curve and required skills for accurate and precise performance are greater compared to traditional surgery [12]. This disadvantage has led to a slow rate of laparoscopy implementation for colorectal surgery, even though this technique has promising clinical benefits [12]. In colectomy procedures, "the number of surgeons capable of performing" laparoscopy is limited, and due to the lack of laparoscopic training models, this number is not increasing [59]. As a result, professionals in the field are researching more effective strategies for training laparoscopic colorectal surgeons.

2.4 Existing Training Models

Current research strategies have led to the design and development of surgical training simulation models. A simulation model is a device "that allows the interactive performance of the trainee in an environment that recreates or replicates a real-world clinical scenario" [60]. Developed simulators for colorectal surgical training can be broken into five main categories: box trainers, virtual reality simulators, cadaver models, synthetic models, and 3D printed models. The pros and cons of each of these simulation models is shown below in Table 1.

Table 1. Pros and cons of the current colorectal surgical training

Types of Simulator	Pros	Cons
Box trainer	• Simple, easy-to-use training model • Helps increasing hand-eye coordination skills • Portable • Relatively inexpensive • Re-usable	• Does not provide realistic surgical skills • Does not mimic the abdominal microenvironment of human
Virtual reality simulator	• Helps increasing anatomical recognition • Helps developing hand-eye coordination skills • Simulates laparoscopic surgical technicalities	• Not portable • High start-up costs • Need ongoing maintenance
Cadaver model	• Most bio-realistic model available currently	• Preservative chemical of the model can be hazardous upon exposure to nose, eyes, or skin • Expensive • Limited supply • Ethical concerns regarding utilize cadaver for surgical training
Synthetic model	• Bio-realistic • Provides a wide range of training for surgical skills	• Expensive • Limited supply • Single-use • Expensive
3D printed model	• Anatomical accurate • Provides personalize assistance for patient conditions and treatments	• Long manufacturing time • Expensive • Lack of bio-realistic materials for the training model • Does not available on the market

2.4.1 Box Trainers

Box trainers are used by surgical residents to acquire fundamental skills for minimally invasive surgery (MIS) outside of the operation room [61]. The model is a simple design that includes a plastic bin with 4 trocar ports (2 ports on each side of the trainer). It also contains a camera to simulate the endoscope. The platform allows users to practice and perfect their skills using laparoscopic instruments while manipulating simple objects. The Fundamentals of

Laparoscopic Surgery (FLS) program was developed to assess the psychomotor skills of residents that are required to perform MIS, such as peg transfer, pattern cutting, ligation loop, and suturing with intracorporeal and extracorporeal knot tying. The testing tasks are shown in Figure 11. The simulation model is portable, relatively inexpensive, increases hand-eye coordination skills, and is re-usable. Even though the physical model is re-usable by itself, the practicing materials need to be replace frequently [61]. Additionally, the box trainer doesn't provide actual surgical operation skills. While they do achieve accurate structural organization of the surgical site, the models do not mimic the native environment, leading to a lack of biomechanical understanding of handling the tissues [61]. Therefore, box trainers, would not be the best option for the technical skills that need to be acquired for laparoscopic surgeries.

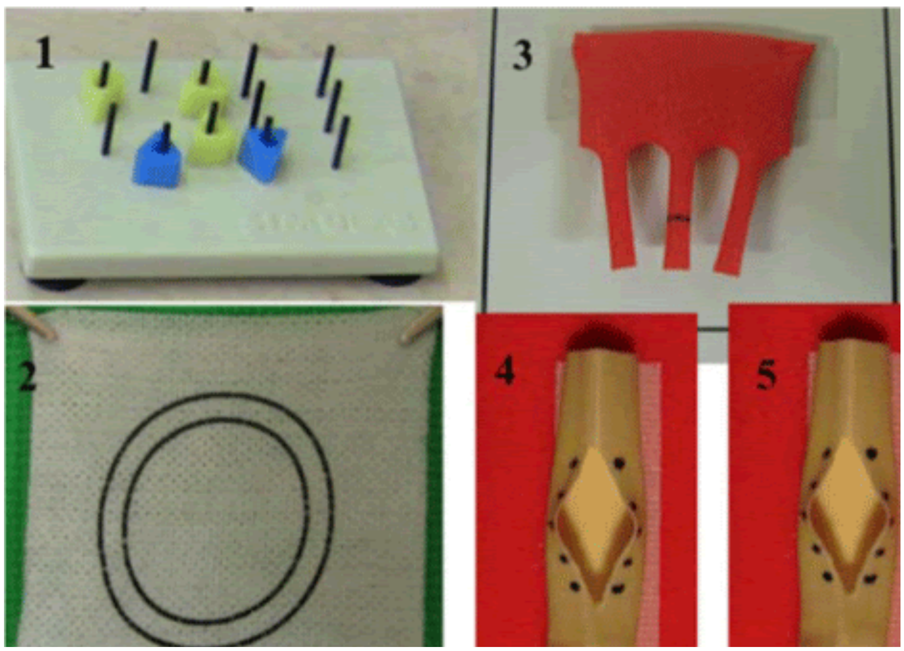

Figure 11: Materials Used in FLS Test to Evaluate Psychomotor Skills [61]

2.4.2 Virtual Reality Simulators

Virtual reality (VR) simulators are set up so that hand held tools are connected to a visual system, such as a computer. The VR screen displays a surgical site, so when the trainee moves the hand held tools, his or her movements are displayed on the screen; this allows for a real-time video performance of a surgery. VR simulators allow the trainee to look at a screen that displays native tissue (which increases anatomical recognition for the trainee) and to develop an understanding of hand eye coordination. Moreover, the procedure can be easily recorded, permitting detailed post-performance feedback, and reused without the need to replace parts [12], [62]. However, the VR system, while it can simulate the technicalities of laparoscopic surgery, the trainee does not receive sensory feedback that matches a true surgical performance [12].

While the Da Vinci® system is used for real-time laparoscopic surgical procedures, this robot system can also be used for virtual reality simulation training. The robot has three components: the console, laparoscopic tower, and patient-side robot, as shown in Figure 12. The console is where the surgeon sits for training and real surgical procedures. The system provides surgeons with a “magnified three dimensional video-scopic view of the operative field and precise articulating laparoscopic instruments” [63]. Training on the Da Vinci® robot is completed in multiple phases. Phase 1 is mandatory for all trainees who intend to perform robotic surgeries with the Da Vinci® system, according to the FDA. This phase happens over two days and is instructed by an employee of Intuitive Surgical. During this training, trainees perform different surgical skills such as knot-tying or suturing using both inanimate objects and animal models. After completing phase 1, the trainees can move forward to the next phases, which include self-guided training and practice until they can proficiently perform each task.

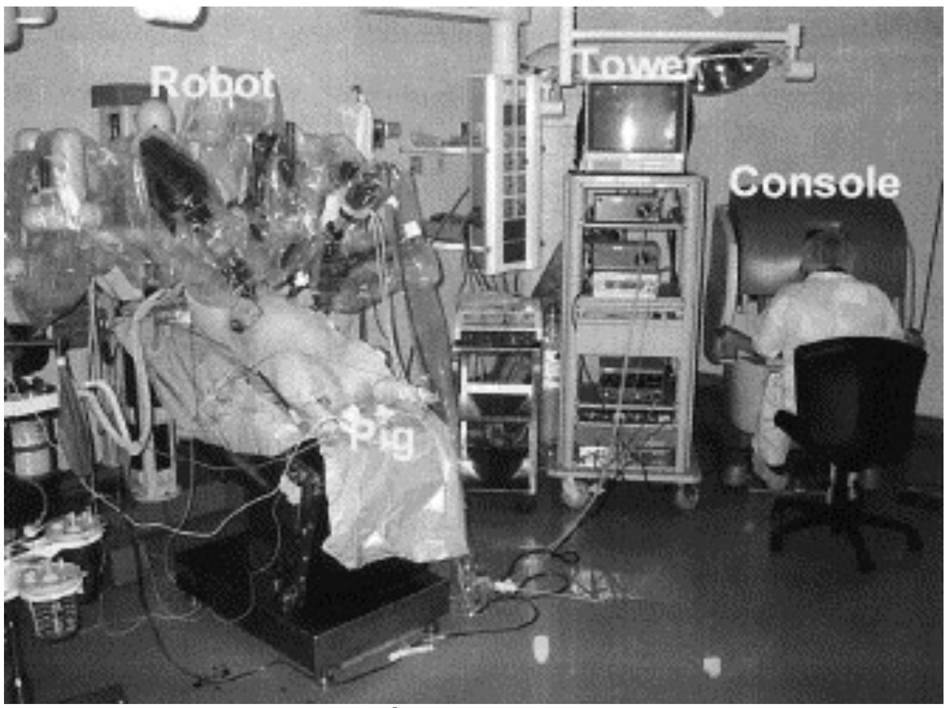

Figure 12: Da Vinci® Robotic System Components [63]

2.4.3 Cadaver Models

Cadaver models have been used in medical training for thousands of years to help learn the anatomy of the human body. Cadavers are human bodies, which have been preserved with the use of various chemicals. These chemicals include formaldehyde, phenol, methanol, and glycerin [64]. Formaldehyde is the major chemical that contributes to the strong smell of the cadaver. Although the chemicals help to preserve cadavers for up to 6 years, they can be hazardous upon exposure via nose, eyes, or skin [64]. As a result, medical students wear personal protective equipment, however, long term exposure to these chemicals, especially formaldehyde, can cause cancer and potentially damage the nervous system [65]. Additionally, these chemicals can cause the tissue and muscle to stiffen making it difficult to practice surgery. Cadavers are also designed only for a single use. Furthermore, a single cadaver costs around $2000 (not including additional storage costs), and the supply of cadavers comes solely from people willing to donate their bodies to science [66]. With cadavers being this expensive and their supply being limited, it is difficult to obtain them.

Animal cadaver models are also being investigated for training laparoscopic surgeons. More specifically, animal models have anatomical differences compared to human models, which could decrease the learning curve for surgical trainees [16]. Finally, there are ethical concerns surrounding these models, which further decreases motivation to utilize cadavers for surgical training in general [62].

2.4.4 Synthetic Models

Synthetic models are constructed out of man-made materials, such as silicone, to create a model used for teaching surgical skills. The realistic qualities of synthetic models range, depending on the particular skills that the model supports. Basic surgical techniques are typically supported by a non-realistic model, whereas more in depth procedural training is supported by a realistic model [67]. The realistic synthetic models allow the trainee to obtain a good understanding of what it is like to use real surgical tools on human tissue [16]. The models can have blood flow and circulation that resemble accurate flow rate and pressures, as well as sensors to simulate patient vitals. The technology and design allows the trainee to receive sensory feedback, and develop minimally invasive techniques. However, these models tend of be extremely expensive, limited, and either single-use or costly to replace parts. Synthetic models are constructed out of man-made materials, such as silicone, to create a model used for teaching surgical skills. The realistic qualities of synthetic models range, depending on the particular skills that the model supports. Basic surgical techniques are typically supported by a non-realistic model, whereas more in depth procedural training is supported by a realistic model [67]. The realistic synthetic models allow the trainee to obtain a good understanding of what it is like to use real surgical tools on human tissue [16]. The models can have blood flow and circulation that resemble accurate flow rate and pressures, as well as sensors to simulate patient vitals. The technology and design allows the trainee to receive sensory feedback, and develop minimally invasive techniques. However, these models tend of be extremely expensive, limited, and either single-use or costly to replace parts. One example of a synthetic model is produced by a company called Syndaver® [66]. The model is a full-body surgical training model with "musculoskeletal, cardiovascular, respiratory, and gastrointestinal system" [68]. There are individual parts that can be removed and replaced as needed, and the model supports different laparoscopic training procedures [68].

2.4.5 3D Printed Models

3D printing techniques have been widely integrated into biomedical research and healthcare within the past few years. As stated previously, the need for a more realistic and cost-effective surgical training models is quite prevalent in healthcare. 3D printing models have emerged as a potential surgical training tool, favored for their anatomically accurate and patient-specific structure. 3D models are developed from medical images of the desired region/organ of the patient. The main imaging technology used are CT scans, MRI, SPECT/PET, ultrasound, and photoacoustic. Once finalized, the 3D structure file must be translated into a language that can be recognized by the printer. This language is a series of coordinates that the printer follows to control the placement of the material [69].

There are three common types of 3D printing: extrusion printing, photopolymerization, and powder binding techniques. Extrusion printing uses a nozzle to extrude the molten material onto a surface, where it cools and hardens again. Materials that are flexible and degrade faster better mimic the internal environment of the human body. Soft plastic polymers mimic the properties of human tissue well and are biocompatible. Therefore, this material is most often used.

In addition to training surgical residents, the 3D printed models can assist with patient education of their condition and treatment, patient-specific implants, and tissue engineering in the field of regenerative medicine. Attending surgeons also use 3D models for intervention planning in radiology and surgery. Prior planning of surgical intervention for cases like abdominal tumors has shown to reduce operation time and improve clinical outcomes.

Due to the novelty of 3D printed surgical training models, there has not been any research on the potential long-term effects of conducting surgeries based on 3D printed models having design errors. Another limitation of this technique is the long manufacturing time, which could take anywhere from hours to days depending on the complexity of the design. Cost benefit analyses have demonstrated that the money saved by using 3D models for intervention planning significantly outweigh the long production time. However, this same analysis has not been conducted for the use of 3D models in surgical training. The last limitation of this training model is the lack of materials that accurately mimic the biomechanical properties of in-vivo structures. Research is currently being done to develop a flexible polymer that can retain the properties of native tissue.

There are limited 3D printed models currently on the market. 3D Systems is a biomedical company that manufactures patient specific 3D training models. They provide a 3D modeling service that allows surgeons to send them a CT or MRI scan of their patient's organ. Then, the company engineers will process, design, and print the respective model. After the model has been printed, it can be shipped back to the surgeon, within one to two weeks, for pre-surgical planning and rehearsal. 3D systems typically print their models using rigid plastic polymers that are ideal for making silicone molds. Specific pricing is not available for these models; however, they are very expensive due to their customization and high quality. Moreover, the models are unable to mimic the biomechanical properties of human tissue, despite their anatomical accuracy [70]. The different types of surgical models will need to make use of bio-realistic materials that accurately mimic human tissue properties, such as hydrogels.

2.5 Need Statement

After investigating the current models on the market for laparoscopic colorectal surgical training, we determined that there is a need to design and develop an inanimate, bio-realistic, cost-effective, and reusable surgical trainer. The model needs to recapitulate normal human tissue through accurately mimicking the rupture and adhesive strength of the organs and tissues within the model. The model must readily allow medical institutions to train their surgical residents without risking patient health. It is anticipated that developing a trainer at a low cost will also aid in increasing the number of laparoscopically trained surgeons in low-income countries where access to appropriate training is limited.

3.0 Project Strategy

3.1 Initial Client Statement

Dr. Thomas Cataldo from Beth Israel Deaconess Medical Center (BIDMC) is the client for this biomedical engineering design project. He presented the design team with the challenge to "Develop a bio-realistic, cost effective, reusable training tool that can be used to accelerate the surgical learning curve for colorectal residents."

3.2 Defining the Stakeholders

While starting the design process and determining our objectives, we identified the stakeholders of our project. Stakeholders are defined as any person, group, or party who is invested in the outcome of an organization and its actions [71]. We divided our stakeholders into three key groups: Clients, Users, and Designers. Figure 13 below represents the hierarchy of our stakeholders from least important (bottom) to most important (top). Clients are people and institutions that sponsor and invest in the project [71]. They have specific wants and needs that must be met to satisfy the purpose of the project. They are our main stakeholders because our team will design the surgical model around the needs of our clients. Our main client and sponsor is Dr. Cataldo, an Assistant Professor of Surgery and Program Director in colorectal surgery at BIDMC. He identified the need for this project leading to the creation of this MQP at WPI. His funding is provided by BIDMC, the other sponsor of this project. Other hospitals that could benefit from this surgical training model are also clients, as they also may have interest in investing in this product. Professor Pins is our final client, as he is our co-advisor for this project, with Dr. Cataldo, who is representing WPI.

Users are stakeholders that are directly impacted by the quality and value of the product [71]. These include surgical residents, medical students, attending surgeons, and simulation lab technicians. All these people will have hands on experience with the product and will benefit from its success. Therefore, it is important that the training model also meets the needs of the users.

The last stakeholders are the designers of this project. This consists of our MQP design team- Shanna Bonanno, Mark Bray, Parima Sharma, Isabelle Sillo, and Amy Tran. We are invested in designing a product that satisfies our stakeholders. We will develop our design by defining specific criteria that align with the stakeholders' wants and needs.

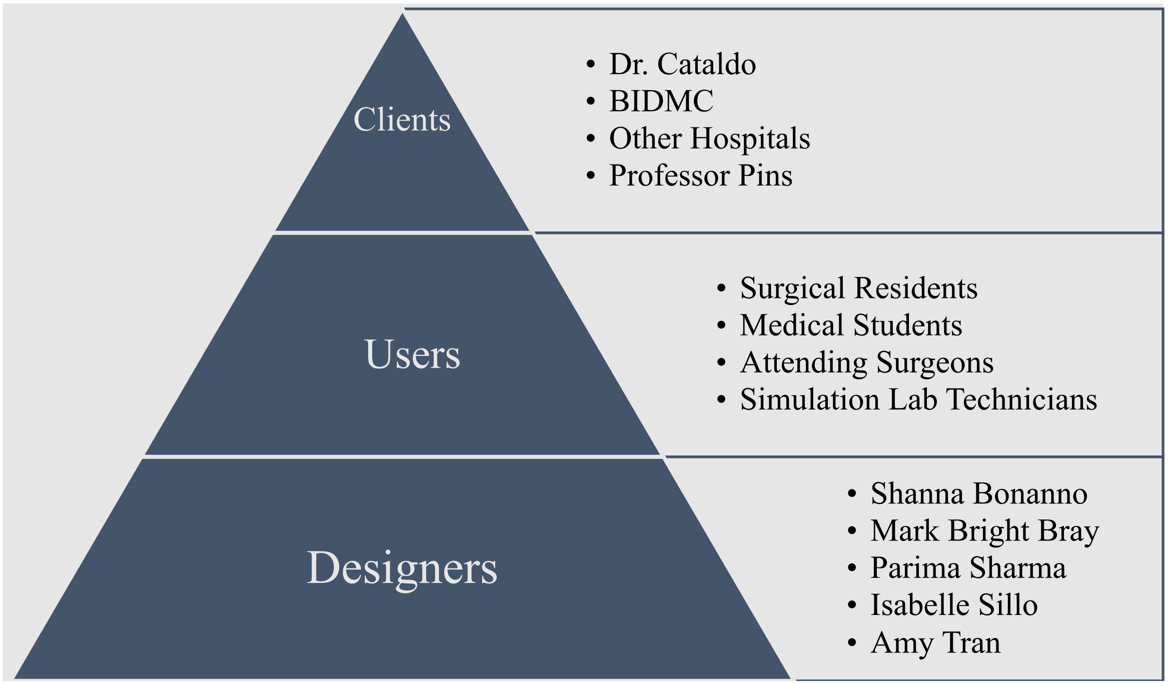

Figure 13: Hierarchy of Project Stakeholders

3.3 Initial Design Objectives

After receiving our initial client statement and determining the stakeholders of our project, our team developed the following initial design objectives for the surgical training model. These objectives are described in Table 2 below. They are bio-realistic, cost effective, and reusable. These were stated directly in the client statement from our sponsor, Dr. Cataldo.

Table 2: Description of Initial Design Objectives

Objective	Description
Bio-realistic	Mimic biomechanical and structural properties of human abdominal organs
Cost Effective	Low cost of manufacturing and replaceable parts
Reusable	Retain function with multiple uses before replacement

3.4 Design Constraints

After meeting with our advisors and stakeholders, a set of constraints were developed. The constraints were divided into two main categories: material and technical. Table 3 shows these constraints.

Table 3: Design Constraints and Descriptions

Constraints		Description
Material	Material Properties	- Materials must not be toxic - Materials must not be flammable - Materials must be able to interact with steel
	Reusability	- The shape/size of the organ must not change - Each part must be detachable for cleaning - Disinfectants should not affect material properties
Technical	Time Limit	- The model must be completed at the end of D2021 term
	Cost	- The total budget must be $1250 or under

The material constraints are important since the phantom must be compatible with the operation room environment. We need to make sure that the model is safe and non-flammable, especially when interacting with surgical instruments. Individual parts should be detachable for cleaning between uses, and the disinfectants should not affect material properties. Additionally, the size and shape of the parts should not change easily and the model should maintain its structural integrity.

Technical constraints of the project include time and resources. The design needs to be completed in one academic year (by May 2021) with a budget of $1250 ($250 per team member). Moreover, the model and its additional parts must be compact and easily portable.

3.5 Final Objectives

Our team further developed and finalized the design objectives for the surgical abdomen. The final objectives include bio-realistic, cost-effective, reusability, educational, and easy to use, and are outlined in sections 3.5.1-3.5.5.

3.5.1 Objective: Bio-Realistic

The model should be bio-realistic and accurately mimic the right upper quadrant of the abdomen with the following organs: transverse colon, duodenum, right kidney, mesentery, stomach, gallbladder, and small intestine. The surgical model should be able to simulate the tissue microenvironment’s mechanical (puncture, peel, and tensile forces) and biofluidic properties (blood, bile, and feces within the organs). This is essential so a medical student can be well-prepared before operating on a real patient.

3.5.2 Objective: Cost-Effective

The model should be cost-effective so the customer (medical schools) is more likely to use it. Specifically, the manufacturing costs of the model and the replaceable parts should be low. Part of this objective is because of the budget for this project. However, keeping the manufacturing costs low makes the fabrication process more efficient and poses potential applications for using the model in developing countries.

3.5.3 Objective: Reusability

The model should be reusable, so it can be used numerous times throughout its life. We want to recover the model after each use, so each medical student gets the same experience with the model. Due to this design criteria, it is possible that individual parts of the model might have to be replaced occasionally for continued functioning of the model.

3.5.4 Objective: Easy to Use

The model should be easy to use as this will appeal to residents. If the model is too complicated, the students might not gain or learn as much. Thus, having a straightforward model that students can quickly learn how to use will be worth more of the user's time and will result in a more efficient learning process.

3.5.5 Objective: Educational

The model should be educational, so it is useful to the medical students. Specifically, the model should allow the medical students to confidently perform skills important during operation. This is an important design criterion to ensure that the model is fulfilling its purpose.

3.6 Evaluating and Ranking Objectives

Once the objective criteria were determined, they were ranked by the users, designers, and our client, Dr. Cataldo. The designers (our MQP team) ranked each of the objectives from most important (1) to least important (5). Then the overall scores for each objective were determined by averaging the individual scores together. A similar process was repeated for the users since a total of 8 residents were interviewed. The individual objective rankings for the users and designers can be seen in Appendix A and B. The client also ranked the objectives, however, these rankings were not averaged since the sample was made up of one individual. In the client's ranking, the numbers are not from 1 to 5. This is due to the client belief that the bio-realistic objective is the highest priority objective that the model should meet; the other objectives are not nearly as important to the client as this one is. Then, the overall scores for the three stakeholders were compiled in Table 4, and the average for each objective was determined. The most important objectives (ones with the lowest rank score) were highlighted for each stakeholder. Bio-realistic was most important to the client, easy to use was most important to the users, and educational was most important to the designers. After taking the averages, we found that the bio-realistic objective, with a rank score of 1.9, was the highest priority design criteria for the model overall.

Table 4: Objective ranking for Various Stakeholders

	Designers	Users	Clients	Avg
Bio-realistic	2.4	2.3	1.0	1.9
Easy to Use	3.2	1.7	4.5	3.1
Educational	2.0	2.0	4.5	2.8
Cost Effective	2.8	4.7	4.5	4.0
Reusability	4.6	4.1	4.5	4.4

A pairwise comparison chart was also completed to rank the design objectives against each other. The pairwise chart can be seen in Table 5. From this analysis, the ranking of the objectives from most important to least is in the following order: bio-realistic, cost effective, reusability, educational, and easy to use. Bio-realistic was again ranked as the highest, which means this will be an important design criterion to consider when making the model.

Table 5. Pairwise Comparison Chart for Design Objectives

	Bio-Realistic	Educational	Cost Effective	Easy to Use	Reusability	Total Score
Bio-Realistic	X	1	1	1	1	4
Educational	0	X	0	1	0	1
Cost Effective	0	1	X	1	1	3
Easy to Use	0	0	0	X	0	0
Reusability	0	1	0	1	X	2

3.7 Revised Client Statement

Develop and design a surgical training model of the right upper quadrant of the abdomen with the following organs: right kidney, small intestine, duodenum, transverse colon, mesentery, stomach, and gallbladder. This model will be constructed out of material that mimics the biomechanical properties of the abdominal tissue. The dimensions of the model will follow a 1:1 model to human organ ratio. Educational survey ratings will determine if the model met its goal of teaching colorectal residents skills they can translate to the OR. Additionally, the model should be easy to use making the training time no more than 30 minutes. The residents will be able to reuse different parts of the model 3-4 times, with each part costing less than $20. Finally, the manufacturing cost of the entire model should be less than $800.

3.8 Project Strategy and Approach

The goal of this project is to develop a bio-realistic, cost-effective, and reusable laparoscopic trainer for augmenting the learning curve for colorectal residents and allow for repetitive practice and education. While this goal guides the team's project strategy, we also kept in mind the project's constraints; namely, this included our project deadline of May 2021, travel and other restrictions due to the COVID-19 pandemic, and budgetary limits. In this section, we discuss our approach to designing the model given our overarching goals and constraints. We present a timeline for development and outline different milestones we would like to achieve for the first iteration of the surgical trainer. Additionally, we briefly mention the concrete steps taken to reach those milestones for the design.

Being cognizant of a project deadline of May 2021, we developed a project management plan and Gantt chart. The chart can be found in Appendix C of this report and an outline of the major milestones for this project is presented below.

Milestone 1: Identify and characterize suitable materials for each organ. This milestone was reached by the end of the third week of B-term 2020. The design team found materials that reflect the biomechanical properties mentioned in section 4.2 and verified the properties of the materials using the Granta EduPack® software, other appropriate testing methods, and current research.

Milestone 2: Come up with design solutions and sketch them using a modeling software. Select the best design and decide on a manufacturing/construction method. This milestone was completed by the first week of C-term 2021. The team came up with different designs for the model, and it was sketched using the modeling software SolidWorks and visualization software Microsoft PowerPoint. Then, the best design was determined based on the design criteria. Manufacturing professionals were also consulted to determine the best practices for constructing phantom organs using the materials specified from milestone 1. Using this information, the team accessed resources available to us, and developed a procedure for constructing each organ.

Milestone 3: Construct an organ and verify fulfilment of design specifications. Iterate with other organs. This milestone was be completed by the end of C-term 2021. The design team followed the manufacturing procedure created as a result of milestone 2 to construct the first organ and verify that it meets the biomechanical and other design specifications determined at the start of the design process. This verification process was be done with appropriate testing. The design team also sought and incorporated feedback from the stakeholders defined in section 3.2. A similar process incorporating the lessons learned from designing the first organ was be used by the design team to create the rest of the organs in the right upper quadrant of the abdomen. Finally, the organs constituting the model were be assembled and assessed for the standards determined at the start of the design process.

4.0 Design Process

4.1 Needs Analysis

After determining the final objectives and final client statement, the team was able to analyze the needs and wants of the project, to better define the scope of the design. First, a list of requirements based on the final objectives was developed. From there, the requirements were organized into two categories: needs and wants. The needs were determined based on the scope of our project considering our objectives and identified constraints. The wants are the additional requirements outside of the scope of our project that could be considered in future developmental stages. The needs and wants were then organized into Table 6 and each requirement is defined as shown below.

Table 6: Design Needs and Wants

Needs	Definition
Upper Right Quadrant Abdominal Organs	Ability to physically resemble the following organs: right kidney, small intestine, duodenum, transverse colon, mesentery, stomach, and gallbladder
Standard Human Organ Dimensions	Ability to meet the size dimensions of real human organs, following a 1:1 model to human organ ratio
Bio-realistic Feedback	Ability to produce a feedback sensory information from the model to the user
Biomechanical Organ Properties	Ability to mimic the biomechanical properties of the tissue environments for each organ
Mechanism that holds the organs together	Ability to produce organ-to-organ adhesion properties that match real human organ-to-organ adhesion properties
Fluid Flow	Ability to incorporate abdominal fluid flow that matched the volume, flow rate, and pressure properties of a real human abdomen
Affordable Materials	Ability to be produced within the designated budget
Incorporates Cost-Effective Replacement Parts	Ability to restore the model to original condition after each use within a designated cost-effect budget
Wants	**Definition**
Entire Abdominal Cavity with Organs	Ability to physically resemble each organ in the entire abdominal cavity
Fluid Flow	Ability to incorporate abdominal fluid flow that matched the volume, flow rate, and pressure properties of a real human abdomen
Abdominal Fat Layer	Ability to incorporate a fat layer enclosing the abdominal organs
Bio-realistic Look	Ability to match real abdominal organs in terms of color and texture
Bio-realistic tissue conductive Properties	Ability to flow current through the model to cauterize the tissue
Real-Time Vital Monitoring	Ability to incorporate sensors that read realistic and real-time vitals during training procedures.

4.1.1 Design Needs

Based on the scope of the project, the team will develop the right upper quadrant of the abdomen. Therefore, the team needs to incorporate the organs that are within the right upper quadrant. These organs include the right kidney, small intestine, duodenum, transverse colon, mesentery, stomach, and gallbladder. In addition to incorporating these organs within the model, the model needs to match organ dimensions, the mechanism that holds organs together, and organ-specific biomechanical properties to provide bio-realistic feedback and fluid flow for the user. The material needs to be constructed from affordable materials to have a low manufacturing cost and, as a result, a low purchasing cost so that our model is within our cost constraints and has a competitive cost on the market. Finally, the model needs to have the ability of being restored to its original condition between uses, and the replacement strategy needs to be cost-effective.

4.1.2 Design Wants

The design wants lie beyond the scope of our project. These are requirements that we would meet if we did not have project constraints, especially in time and budget. We would want to develop the entire abdominal cavity incorporating each organ and the abdominal fat layer enclosing the model. We would also want to have real-time vital monitoring throughout the model. In addition, we would have liked the model to not only feel bio-realistic, but look bio-realistic. Finally, the model would have incorporated electric properties to simulate tissue cauterization.

4.2 Functions and Specifications

The objectives and their corresponding functions and specifications are diagrammed in Figure 14.

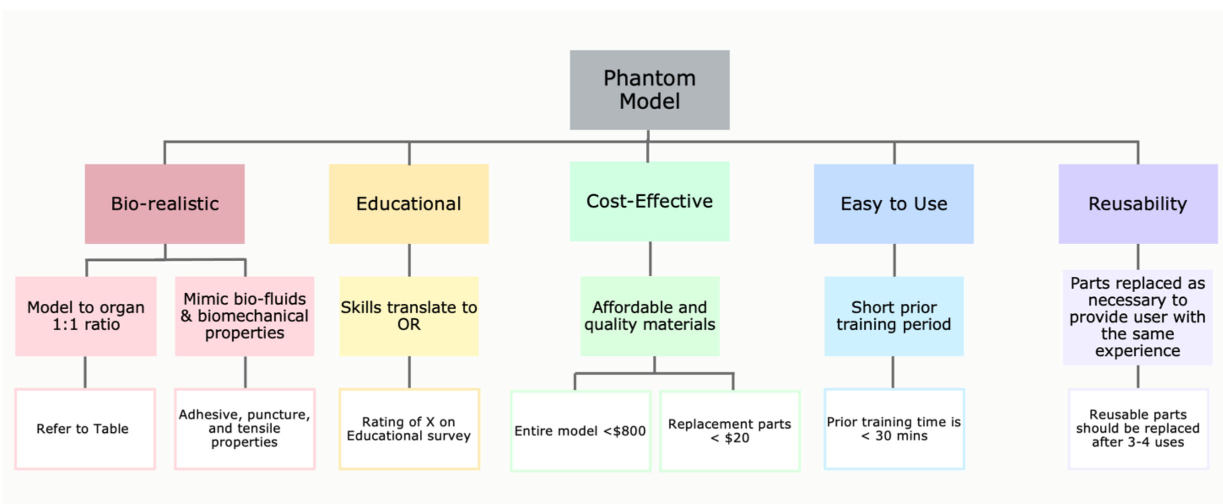

Figure 14. Objectives, Functions, and Specifications

The tree diagram shows the major objectives for the project (bio-realistic, educational, cost-effective, easy to use, and reusable). Each objective is broken down into functions and specifications that serve as a quantitative measure of that objective.

To make the model bio-realistic, it is important for there to be a function stating to have the model to human organ ratio be 1:1. This is important so medical students can practice on organs that are life size, which will accurately represent the patient during operation. Table 7 shows the major organs that our model will have and their corresponding sizes. Additionally, another function for the bio-realistic objective is to make the model mimic biomechanical properties of the organs. With this criterion, the medical student will have accurate sensations when interacting with the model. Table 8 shows the major organs and their respective biomechanical properties, which were found from literature.

Table 7. Right Upper Quadrant Organ Sizes

Organ	Size
Gallbladder	Length: 7-10 cm Width: 5 cm Volume: 30-80 mL [43]
Stomach	Volume: 1000-1500 mL Wall thickness: 0.2-0.5 cm Widest length: 10 cm [38]
Mesentery	Length: 15 cm Width: 20 cm [33]
Transverse Colon	Length: 45 cm Diameter: 7 cm [24]
Duodenum	Length: 25 cm [30]
Small Intestine	Length: 700 cm Width: 3 cm [30]
Right Kidney	Length: 10.85 ± 1.22 cm [47]
Liver	Size: 10 cm (males) [42]

Table 8: Right Upper Quadrant Organ Biomechanical Properties

Organ	Mechanical Properties
Gallbladder	Elastic modulus: 641.20 ± 28.12 kPa (axial) Elastic modulus: 255 ± 24.55 kPa (transversal) [44]
Stomach	Max Stress: 700 KPa (axial) Max Stress: 500 KPa (transversal) Destructive Strain: 190% (axial/transversal) [31]
Mesentery	Mesocolon Tissue Strength: 3552 ± 803 kPa Small Intestinal Tissue Strength: 1595 ± 461 kPa [36]
Transverse Colon	Burst Strength:1223 ± 701 g Tensile Strength: 98 ± 57 g/mm^2 [28]
Duodenum	Max Stress: 900 kPa Destructive Strain: 140% [31]
Small Intestine	Max Stress: 900 kPa Destructive Strain: 140% [31]
Right Kidney	Elastic Modulus: 180.32 kPa (axial/transversal) Failure Stress: 24.46 kPa (axial/transversal) [48]
Liver	None

The educational objective can be achieved by the function of having the skills from the model be translatable to the operation room. For the model to make an impact, the students must be able to apply the skills they learn from the model to a real patient. Ratings from educational surveys can be used to quantify the students' opinions on how helpful they thought the model was in training them for operations. Students will be asked to rate the process of practicing with the model on a scale from 1 to 5. If the average score is greater than 3, then we will deem the model as successful. However, if the average score is less than 3, then we will have to alter the model accordingly.

Another objective was that the model should be cost-effective, and the corresponding function is that the quality materials used to make the model should be affordable. After looking into the literature, we determined that the manufacturing cost for the entire model should be less than $500, and that the replacement parts should be less than $20 [72] [73]. Additionally, the total cost of $500 is within our MQP budget of $1250.

We also wanted to make our model easy to use, and the resulting function was to have the training period be short. Specifically, we want to make the training period less than 30 minutes. According to our interviews, most residents spend anywhere from minutes to an hour getting trained on how to use a model. We are aiming to make our model have a training period that is on the lower side of that range.

The final objective is reusability, and we intend to meet this criterion with the following function: replacing the parts of the model as necessary to provide all student users with the same experience. The specification for this function is to have the reusable parts be replaced after 3 to 4 uses [73].

4.3 Conceptual Designs

Figure 15 shows an image of the SolidWorks assembly of the abdominal model. For the sake of the design, the dimensions of the box trainer were arbitrarily assigned as ~23 by 30 by 12 cm. Since we will be modeling the right upper quadrant of the abdomen, our model will include the following organs: gallbladder, stomach, mesentery, transverse colon, duodenum/small intestine, and right kidney. All these organs can be seen in the design. This design shows the entire colon and small intestine although only the right upper sections of these organs will be needed. The esophagus is connected to the stomach, although this organ is positioned mostly outside of the box since we will not be modeling the esophagus in this project. All organs are in their anatomically correct positions in the box trainer. Each individual organ CAD drawing can be found in Appendix D.

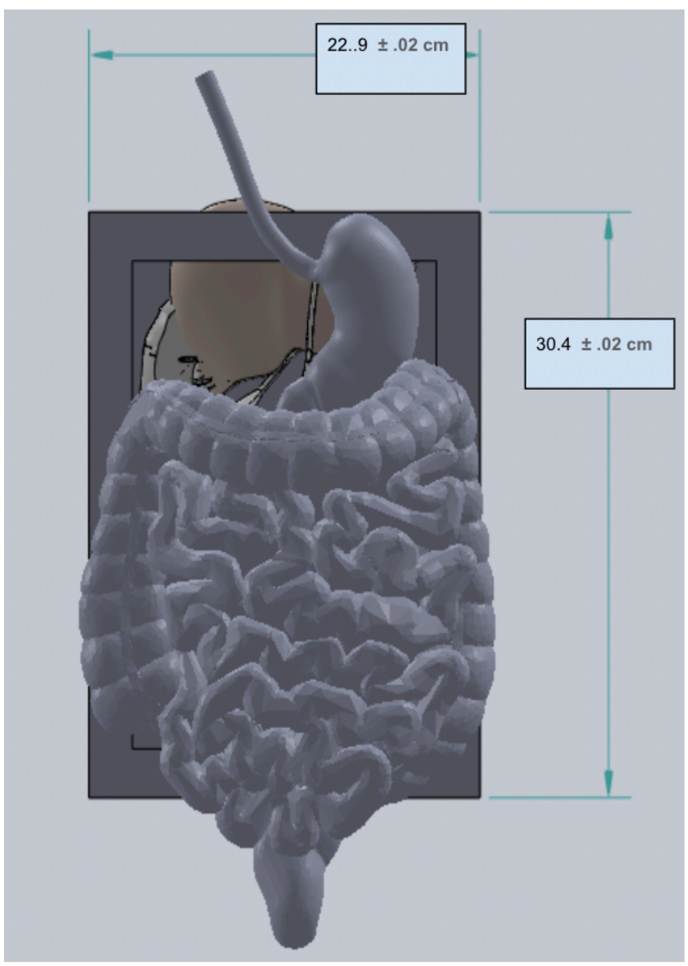

Figure 15. SolidWorks Conceptual Design of the Model.

Figure 16 shows another conceptual design of the abdominal model using arts and crafts supplies. The team attempted to model by hand the individual components that would be included in the model and arranged the organs in a shoe box. The organs depicted in Figure 16 include the liver, right kidney, gallbladder, stomach, duodenum, the rest of the small and large intestine, and the mesentery.

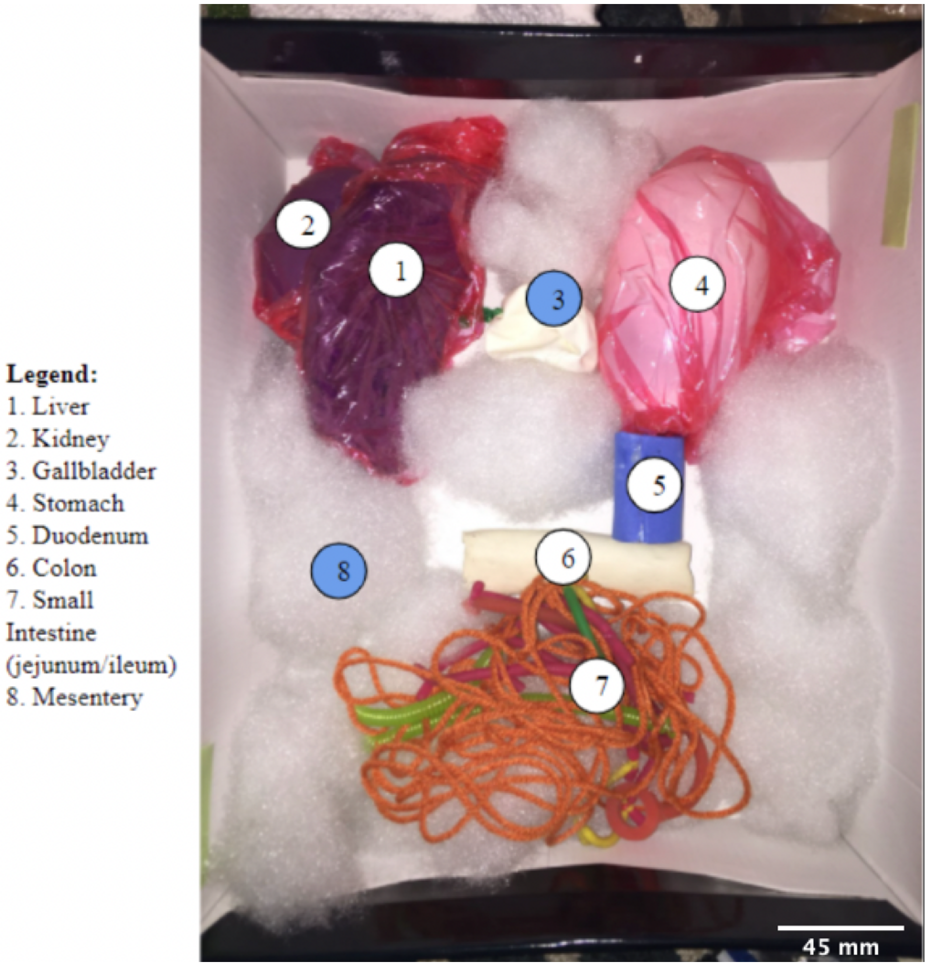

Figure 16: Conceptual Design of the Abdomen Using Arts & Crafts Materials

Another conceptual design was that of a model with specialized materials. In this design, each organ would be made of materials that have mechanical properties similar to their real-life counterparts. Then, all the organs would be put in the box trainer. A description of specialized materials for each organ is given below.

As seen in Table 8, the gallbladder has an axial elastic modulus of 641.20 ± 28.12 kPa. According to Granta EduPack®, other materials that have similar axial elastic moduli include flexible polymer foam and isobutylene isoprene rubber (IIR) [74]. Thus, we will perform preliminary tests on samples of rubber and foam in order to find appropriate material candidates to mimic the gallbladder. Furthermore, the bile inside the gallbladder is quite viscous, leading to the possible use of oil, honey, or other viscous liquids.

Based on literature studies, the biomechanical properties of the stomach include a maximal axial stress of 700 kPa, a maximal transversal stress of 500 kPa, and a destructive strain of 190% (axial/transversal). The average human stomach has the following dimensions: 13 cm width (range 9–16 cm), 15 cm thick (range 10–20 cm) and 10 cm high (range 6–15 cm). Based on Granta EduPack ®, a few materials that will be evaluated for the stomach include silicone, polyurethane, latex, and hydrogel.

The mesentery tissue can be divided into different sections including mesocolon and small intestinal mesentery. The tissue strength of the mesocolon and small intestinal mesentery is 3552 ± 803 kPa and 1595 ± 461 kPa respectively (Table 8). Appropriate materials for the mesocolon section based on the tissue strength properties are flexible polymer foam, rigid polymer foam, and butyl rubber Isobutylene-isoprene [74]. Moreover, materials that could be used for the small intestinal mesentery are flexible polymer foam and rigid polymer foam [74]. The mesentery will be part of all the fat surrounding the organs. Gel-like substances, such as glycerin or gelatin, could also be considered for the fat/mesentery around the organs. The water composition and stickiness of the gel would be adjusted accordingly.

Material selection for the transverse colon will be determined by aligning the mechanical properties between a biological transverse colon with the materials. Literature states that burst strength and tensile strength of the transverse colon were measured to be 1223 ± 701 g and 98 ± 57 g/mm^2 respectively [28]. In addition, the transverse colon of a mouse model will be tested using the Instron 5544. Tensile testing will be performed via ASTM standard D412-16. Mechanical properties will be derived and analyzed from this test and compared against literature. Once this has been completed, materials will be selected. Currently, based on solely literature research materials under consideration for the development of the colon include casting silicone rubber, polyethylene, polypropylene, latex penrose drain, and low-density polyethylene foam.

Appropriate materials for the duodenum are selected based on the mechanical properties of the organ, 0.9 MPa for maximal stress and 140% for destructive strain. Flexible polymer foam is reported to have similar tensile properties as the duodenum, according to values obtained from Granta EduPack ® [74]. Therefore, preliminary test will be performed to help determining if polymer foam is a suitable material. The fabricated organ will be hollowed and contain viscous liquid to mimic intestinal substances. Table 8 shows that the biomechanical properties of the right kidney include an elastic modulus of 180.32 kPa and a failure stress of 24.46 kPa. According to Granta EduPack ®, suitable materials include gelatin, silicone elastomers, polyurethane, natural rubber, elastin, and flexible polymer foam. Thus, the team will begin by testing small quantities these materials to verify their properties and experimenting with how they may be molded or manufactured into the shape and size of a kidney.

4.4 Alternative Designs

Once the component materials for each organ was selected, with preliminary testing that will be described in Chapter 5, the team focused on how the model might be put together with respect to how the final product would be presented while keeping the functions and specifications mentioned in Figure 14 in mind. The team developed three designs and evaluated them using a Pugh Selection Matrix to select the best one. The first design is shown in Figure 17 below.

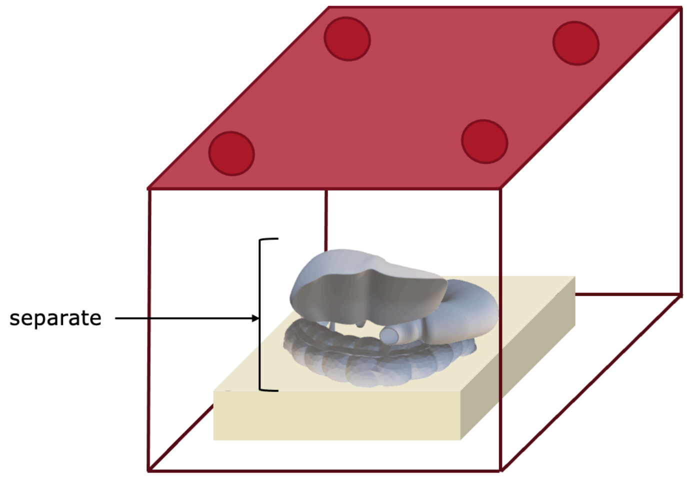

Figure 17: Alternative Design 1 of the Surgical Phantom Box Trainer

Design 1 is as follows: manufacture each organ individually and place each organ separately in a designed abdominal container in their correct anatomical positions. The organs would be supported by surrounding organs and encapsulated in a gel-like substance that would serve as the mesentery. The benefits of this design are that it allows the model to be bio-realistic, cost-effective, and easy to use since component organs would be individually assembled and can be replaced separately. The second design is shown below in Figure 18.

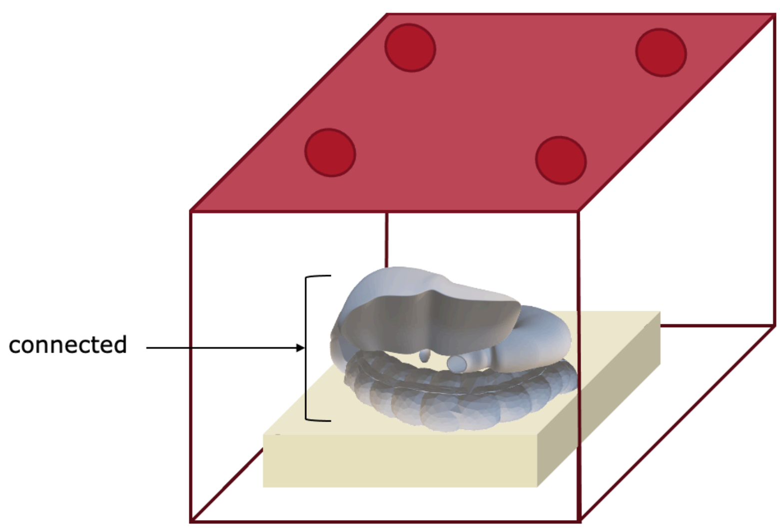

Figure 18: Alternative Design 2 of the Surgical Phantom Box Trainer

Design 2 is as follows: manufacture each organ individually and connect them to each other to be placed into the abdominal container as one unit. This model would have two variations: have the connected organs float freely in the gel-like substance or connect the organs to the wall of the abdominal container. This design shares the same benefits as the first design but reduces the reusability of the model since component parts could not be easily replaced. The third design can be seen below, in Figure 19.

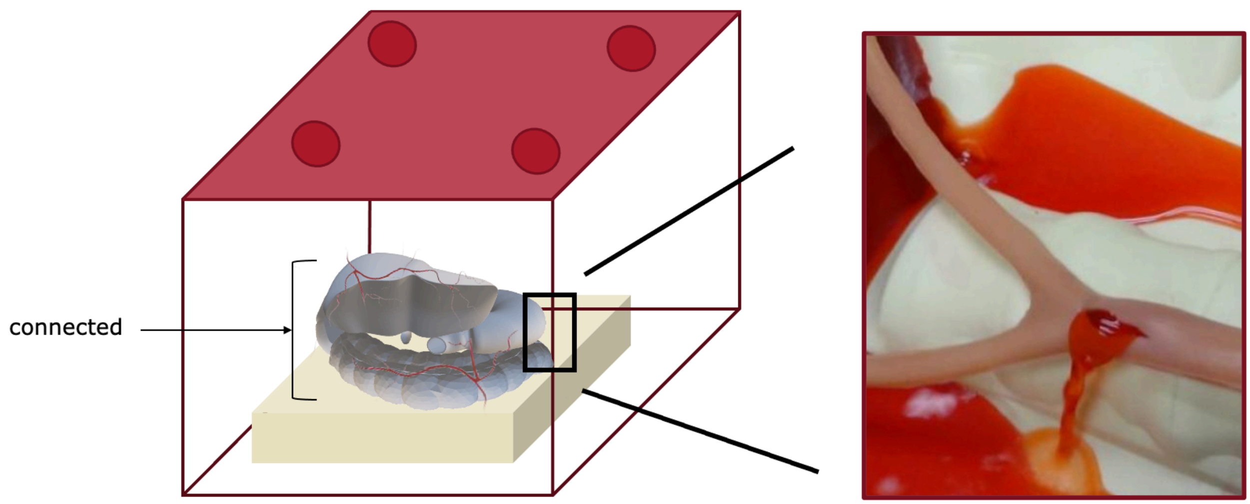

Figure 19: Alternative Design 3 of the Surgical Phantom Box Trainer

Design 3 is as follows: manufacture each organ individually and design the model to provide haptic feedback to the user or produce bodily fluids in response to punctured tissue. This model, like the first and second designs would achieve the objective of being bio-realistic and cost-effective, but in practice would likely not be as reusable since a single punctured vessel or organ could not be replaced as easily and would hinder multiple students from practicing on the model.

Table 9 shows the Pugh Selection Matrix that was used to select the best design. Each of the designs were compared to the baseline model. The baseline model that was used was the synthetic Syndaver® model, which was described in the background section. All the designs were compared to the baseline model based on each design objective. A score of +1, 0, or -1 was put in each cell if the design was better than, the same as, or worse than the baseline model, respectively. Weights were assigned to each design objective, with the highest number going to the most important design criterion. The weights were assigned from the Pairwise chart accordingly, with bio-realistic having the highest weight. Finally, the total score for each design was calculated by taking the product of the score in the cell with the weight for the corresponding objective. All the numbers were added to give the total score for a given design. The Pugh Selection Matrix shows that design 1 (model having separate organs in the training box) has the highest score of 10. Thus, this is the design we moved forward with in the design process.

Table 9. Pugh Selection Matrix

Design Objective	Weight	Baseline: Syndaver® Synthetic Model	Design 1: Separate Organs in Abdominal Container	Design 2: Connected Organs in Abdominal Container	Design 3: Model with more Bodily fluid/Blood and Haptic Feedback
Bio-Realistic	5	0	+1	+1	+1
Cost Effective	4	0	+1	+1	+1
Reusability	3	0	0	-1	-1
Educational	2	0	0	0	0
Easy to Use	1	0	+1	+1	-1
Score		0	10	7	5

5.0 Final Design Verification

5.1 Quantitative Experiments

The following sections contain test methods and set-up procedures to conduct two types of tests (1) baseline testing to understand the mechanical properties of the biological tissue that must be recapitulated in the model, and (2) testing on synthetic material candidates to fabricate the model. Three types of tests provided a comprehensive understanding of the mechanical properties to determine which materials should fabricate the surgical trainer. The tests included a tensile test (ASTM D412-16), puncture test (ASTM D4388), and peel test (ASTM D903-98). Each test will be justified and described in detail in sections 5.1.1, 5.1.2, and 5.1.3, respectively. For tensile test ASTM D412-16, a testing rate of 150 mm/min was used. For puncture test ASTM D4388, a testing rate of 300 mm/min was used. For peel test ASTM D903-98, a testing rate of 150 mm/min was used. Each specimen had a sample size ranging from n=1 to n=6 based on availability, due to cost restraints.

The baseline test was performed using dissected bovine organs, including the colon, small intestine, and mesentery. Baseline data for the other organs that are included in the model were determined from literature. To prep the bovine samples, large sections of the colon, small intestine, and mesentery were removed from the specimen. For the colon and the small intestine, a longitudinal cut was made to expose the inner lining of the organ. Next, the section was cut into rectangular samples, and hydrated in saline solution until testing. For the mesentery, a section of tissue attached to mesentery was dissected from the specimen and sutured to the peel fixture, shown in Figure 27.

Synthetic material candidates for tensile and puncture were selected based on a hypothesized similarity in mechanical characteristics from initial applied force until failure based on research findings; and material candidates for peel testing were selected based on their hypothesized similar adhesion forces based on research findings. Material samples were prepped for tensile and puncture by cutting rectangular sections and securing the samples to the test fixture for each respective test. For peel testing, a base material of Ethylene-Vinyl Acetate (EVA) foam was used to compare the applied adhesive material. Two rectangular sections of EVA foam were used per test. A layer of adhesive material was placed between the two foam pieces. The material was allowed to dry for the stated dry time provided by the manufacturer for the adhesive product before testing.

5.1.1 Tensile Test

While there are recorded mechanical properties in literature for some of the organs, testing still needed to be performed to gather enough baseline data to select materials for the model. Therefore, the mechanical properties of biological organs needed to be tested and compared against mechanical properties of different materials to select the materials that align with each of the organs in the model. To collect data on mechanical properties, tensile testing was performed. Tensile testing is a destructive test where a sample is subjected to controlled uniaxial tension until failure to quantify different mechanical properties that characterize the sample. For the purposes of this project the following mechanical properties were calculated for each of the samples: ultimate tensile strength (UTS), strain at failure, load to failure, tangent modulus, and compliance. UTS is the maximum stress that a material can withstand before it fails and begins to plastically deform. Load at failure is the maximum force that a material can withstand before it fails and begins to plastically deform. Strain to failure is the length that the material can elongate from its starting point before it fails and begins to plastically deform. Tangent modulus is the tangent slope of the stress vs. strain curve to characterize the elasticity of the sample. Tangent modulus was used because we could not assume Hooke's law would allow for an accurate modulus calculation, since the materials being tested were not linear isotropic materials. Finally, compliance is the inverse of modulus. The standard used for tensile testing on biological tissue and synthetic materials was ASTM D412-16, which is the "Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers—Tension" [75]. The tests were conducted in Goddard Hall room 207 at Worcester Polytechnic Institute using the Instron 5544 with the uniaxial grips. The basic set up for uniaxial tension testing is shown in the schematic in Figure 20. The protocol for this setup can be found in Appendix E.

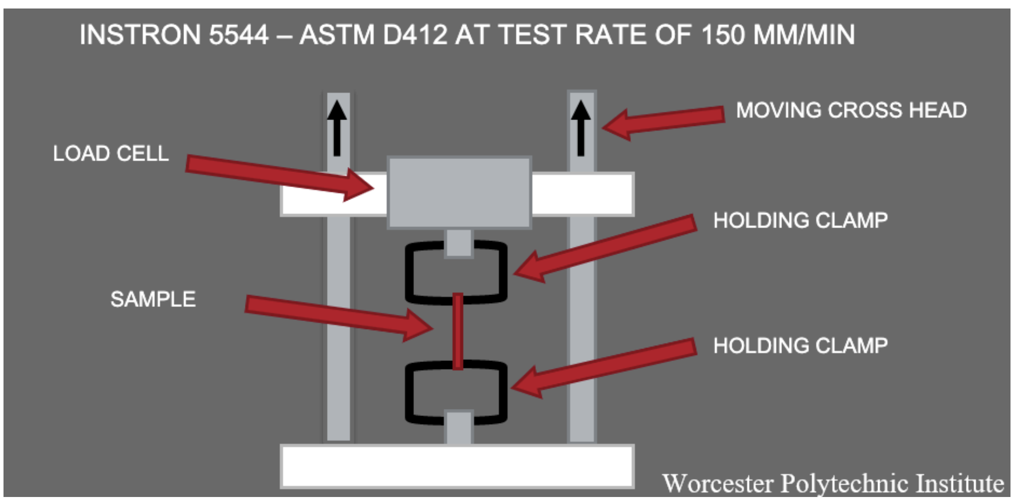

Figure 20. Instron 5544 Tension Testing Set Up

The samples were cut into straight rectangular sections, following ASTM D412-16 Test Method A, and the length, width, and thickness of each of the samples were recorded, which can be seen in Appendix F and G. Biological tissue testing was performed using a bovine specimen purchased from the Blood Farm in Groton, MA. The GI tract and mesentery were dissected from the cow's abdomen by the facility and packaged in a trash bag and in a Styrofoam™ container for transport. The specimen was stored in a refrigerator at 4 °C for about 12 hours. After this time, the specimen was removed from the fridge and kept at room temperature while smaller sections were dissected for testing. This process was conducted in a strict 12-hour window of time to maintain freshness.

For bovine tensile testing, rectangular samples of the following organs were tested: colon, small intestine, and mesentery. The bovine colon and small intestine were prepped following steps one through four in Figure 21, while the mesentery was prepped following steps two through four. For synthetic tensile testing, the following materials were tested: green foam, Smooth-On OOMOO™ 25 Silicone, Polydimethylsiloxane (PDMS) (Sylgard), stove silicone, GLAD® Cling Wrap, sausage casing, parafilm, and ethylene vinyl acetate (EVA) foam. The product names, manufacturers, and catalog numbers can be found in Appendix H. The synthetic materials were prepped following steps two and three in Figure 21. The protocol for this setup can be found in Appendix E.

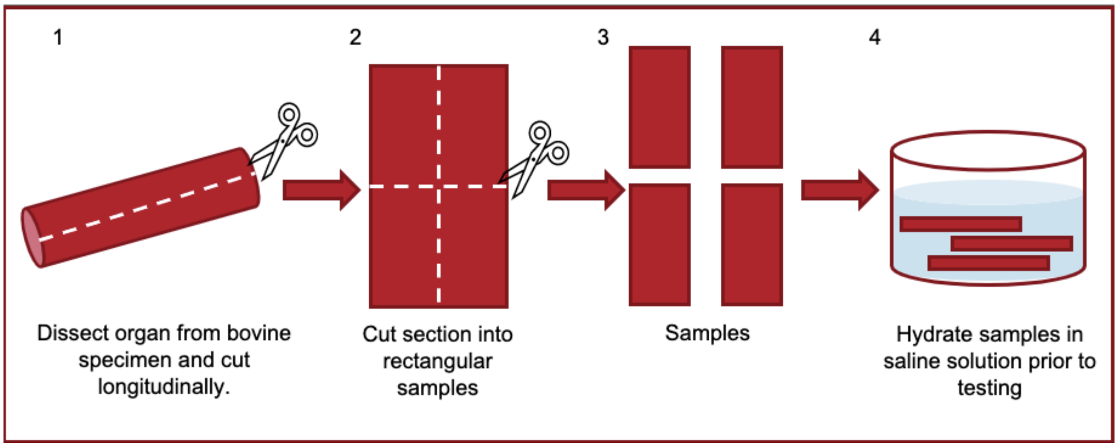

Figure 21. Prepping Samples for Tensile Testing

The tensile test was performed three times per sample. The length, width, and thickness of each samples were measured three times with a Mitutoyo digital caliper (± 0.01mm) and the average values were recorded. To avoid damage to the force transducer, the safety stop was set to an appropriate position. Each specimen was mounted onto screw-action grips with diamond grip faces on an Instron 5544 screw-driven machine, as shown in Figure 22.

Figure 22. Tensile Test Set Up with Bovine Colon Sample on Instron 5544

BlueHill3 software was used to set up the tension test method. The strain rate for all of the samples was 150 mm/min. Prior to running each test, the load was balanced and the extension was set to zero. After running the tests, the raw data was exported for analysis, which is discussed in section 5.2.1 Tensile Test Results.

5.1.2 Puncture Test

The team determined that characterizing the puncture resistance of the materials used for each organ would be an important component of the biomechanical properties of the organ. ASTM standards D4833 was selected to characterize the puncture resistance of the materials being considered for each organ. ASTM standard D4833 is designed to measure the index puncture resistance of geomembranes, which is also known as a synthetic membrane material. As part of the testing method, a test specimen is clamped between 2 plates of a puncture apparatus. A schematic and description of the apparatus is shown in Appendix I. Each plate has a circular hole for the puncture tip to pass through and rupture the specimen. The puncture apparatus is placed beneath the Instron 5544 during the test, and the team built one using wood. The entire puncture test set up can be seen in Figure 23. The puncture tip is attached to the Instron 5544 via grips, and it moves downward with a rate of 300 ± 10 mm/min. Once the puncture tip ruptures the specimen, the maximum force is recorded, which represents the puncture resistance of the specimen [76]. The protocol for this setup can be found in Appendix E.

Figure 23: Puncture Test Set Up

The method was performed using the puncture tip shown in Figure 24 fabricated by the team. After the test, the Instron 5544 produces a graph, such as the one shown in Figure 25, with force against penetration distance of the specimen. A total of 3 trials was conducted for each specimen.

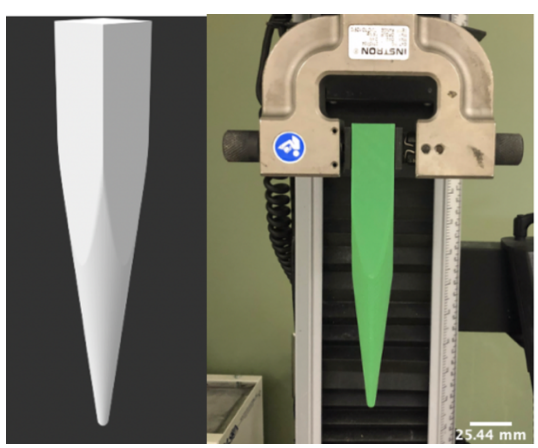

Figure 24. Puncture Tip Fabricated by the Team for Puncture Testing

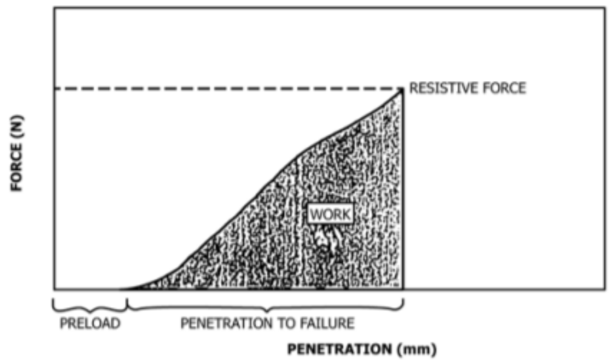

Figure 25. Force-Penetration Relationship Using ASTM Standards D4833 [76]

5.1.3 Peel Test

An important aspect of abdominal surgery is the movement and separation of adjacent organs. This allows the surgeon to see the organs from different angles and access different parts of the abdomen. The surgeon does this by peeling apart organs that are stuck together by fluid in the space between the organs, using blunt surgical tools. This was modeled in the mechanical properties testing to identify the peel strength of various adhesives that can mimic the interstitial fluid. The team created the peel test method based off the ASTM standard D903-98 and D1876-08 [77] [78]. This method used a combination of the setups shown in Figure 26 below. The protocol for this setup can be found in Appendix E.

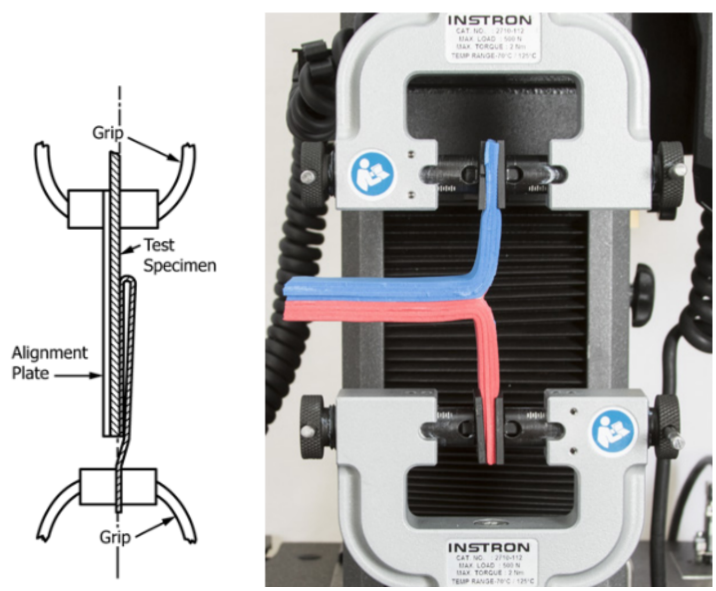

Figure 26. ASTM Standard D903-98 [77] and D1876-08 [78] Instron-Specimen Setups

The Instron-Specimen setups above show the placement of two specimen samples in the Instron 5544. The ASTM standard D903-98 uses one flexible specimen and one either rigid or flexible specimen that are bonded together [78]. From various preliminary tests, the team decided to use a rigid specimen for the second one, as it will eliminate the elastic deformation of the specimen materials and give the most accurate peel strength of the adhesives. The ASTM D1876-08 is ideal for acquiring peel strength because it pulls two flexible specimens apart in a horizontal direction (90-degree angle), similar to surgery, whereas the ASTM Standard D903-98 applies a vertical pulling force (180-degree angle) [77] [78]. Therefore, these ASTM Standards were combined to create the Instron-Specimen setup shown below in Figure 27 to test peel strength of the chosen adhesives.

Figure 27. (A) STL file of L Shaped Rigid Specimen for Peel Testing. (B) Setup of the Peel Test with the L Shaped Rigid Specimen

This setup used an L shaped 3D printed PLA piece as the rigid specimen. The dimensions of the long leg were 25.4 cm length x 3.8 cm width x 0.3 cm thickness. The dimensions of the short leg were 0.3 cm x 3.8 cm x 2.5 cm. The flexible specimen was made of a strong, flexible Ethylene-Vinyl Acetate (EVA) foam. The dimensions of the flexible piece were 20.3 cm length x 2.5 cm width x ~0.4 cm thickness. The application of the different adhesives varied on their preparation directions; however, they all bonded the flexible and rigid specimen with the same method. The adhesive was applied from the end of the flexible specimen to 15.2 cm inwards. Then the end of the flexible piece was placed on top of the long leg of the rigid specimen at the free end and were pressed together as needed to bond them. The specimen must be placed end to end so they can be separated similarly to the ASTM Standard D1876-08 [78]. The specimens were left to dry if needed, and then placed into the Instron 5544 grips.

The Instron was preset with a tensile strain test method on BlueHill3 and a grip separation rate of 350 mm/min. Force was applied at a rate of 50 mm/min [77]. The test method was set to record the modulus, yield load, and tensile strain. The short leg of the rigid specimen was placed in the bottom clamp, allowing the long leg to protrude to the side and create a horizontal pulling force. The free end of the flexible specimen was bent back at a 90-degree angle and placed in the top clamp, as seen in Figure 27B [78]. Three trials were run on each adhesive.

The adhesives tested were double sided tape, Nano Grip tape, rubber cement, Loctite® spray glue, spirit gum, gelatin-glycerin, hydrogel patch, hydrogel collagen patch, and hydrogel liquid. The product names, manufacturers, and catalog numbers can be found in Appendix H. The double sided, electrical tape, and Nano Grip tape did not require additional force or drying time to stick the specimens together. However, the rubber cement and Loctite® spray glue specimens were pressed together for 1 minute and allowed to dry for 5 minutes before testing. The sample size of each material varies from 3 to 6 specimens.

In order to obtain standard peel strength values to compare the adhesives to, animal samples were dissected and tested. The bovine specimen obtained from the Blood Farm in Groton, MA was cut into samples with the dimensions: 0.25cm width x 1.25cm length x 0.06cm thickness. For animal peel testing, rectangular samples of the colon-mesentary were used. Three samples were produced for the testing. These samples were then loaded onto the Instron machine, the top layer was tightly hold by the top clap and the bottom layer was stitched to the rigid specimen to avoid any slipping before tightly secure to the bottom clap. This test was conducted on chicken breast samples to test its validity and feasibility. This setup is shown below in Figure 28.

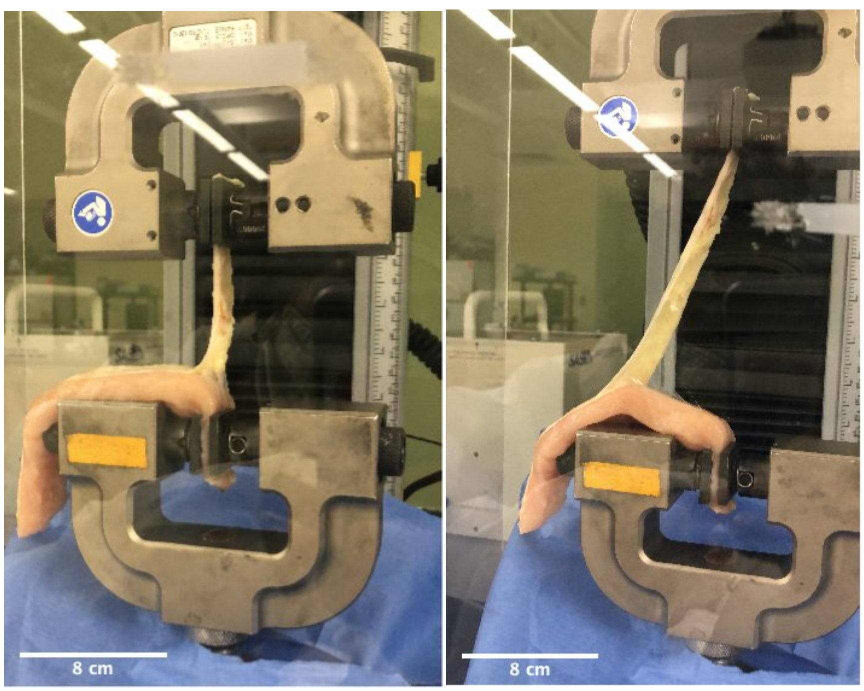

Figure 28: Preliminary Setup of Peel Test with Chicken Samples

5.2 Quantitative Test Results

Three quantitative tests were performed: peel, puncture, and tensile tests as discussed in section 5.1. These tests were used to compare the material data to the bovine data, allowing appropriate material selection for each organ. The results for the individual tests are described in the following sections. After comparing the material data with the bovine data, the material that best matched the properties of the native tissue was selected for each component. The following table shows the final material choices for each component. These were chosen based on their statistical equivalence to the respective bovine organ sample, revealed through statistical analysis. Sections 5.2.1-5.2.1 will discuss the results for each of the three tests individually.

Table 10. Final Material Selection

Material	Model Part	Material Properties
OOMOO™ 25 (Smooth-On SMOoomoo25)	Mesentery, Stomach, Liver, Small Intestine	UTS: 0.46 ± 0.080 MPa (n=3) Puncture: 14 ± 2.3 N/mm (n=2)
Dragon Skin™ 10 (Smooth-On 751635823419)	Kidney	UTS: 3.3 MPa Puncture: 23 ± 1.2 N/mm (n=2)
Dragon Skin™ 20 (Smooth-On 4336899332)	Gallbladder	UTS: 3.8 MPa Puncture: 27 ± 1.4 N/mm (n=2)
Agilus30™ Shore A (Stratasys FLX9840)	Colon	UTS: 2.4-3.1 MPa

5.2.1 Tensile Test Results

Tension testing was performed to characterize the mechanical properties of biological tissue to compare with the mechanical properties of synthetic materials, in order to select bio-realistic materials for the model. The average mechanical properties of ultimate tensile strength, tangent modulus, compliance, load to failure, and strain to failure for bovine samples and synthetic materials is shown in Table 11. Stress vs strain graphs and sample dimensions are located in Appendix F and G.

Table 11. Average Tensile Mechanical Properties of Bovine Samples & Synthetic Materials

Sample	Sample Size (n)	Avg UTS ± SD (MPa)	Avg Tangent Modulus ± SD (MPa)	Avg Compliance ± SD	Avg Load to Failure ± SD (N)	Avg Strain at Failure ± SD
Bovine Colon	6	1.81 ± 0.71	19.99 ± 10.65	0.07 ± 0.06	53.18 ± 14.12	0.18 ± 0.12
Bovine Small Intestine	6	0.58 ± 0.19	3.04 ± 2.55	2.63 ± 1.47	27.22 ± 16.71	0.48 ± 0.23
Bovine Mesentery	3	0.34 ± 0.11	1.56 ± 0.70	1.49 ± 1.07	30.46 ± 8.16	0.29 ± 0.08
Green Foam	3	0.12 ± 0.03	0.12 ± 0.03	8.45 ± 1.96	40.98 ± 3.06	0.98 ± 0.09
Smooth-On OOMOO™ Silicone	3	0.46 ± 0.08	1.55 ± 0.31	0.66 ± 0.12	35.27 ± 3.10	0.34 ± 0.05
Polydimethyl-siloxane (PDMS) (Sylgard)	2	0.49 ± 0.25	3.41 ± 0.20	0.29 ± 0.12	62.88 ± 32.35	0.14 ± 0.08
Stove Silicone	3	-	67.46 ± 8.76	-	-	-
GLAD® Cling Wrap	6	-	-	-	2.43 ± 0.10	-
Sausage Casing	3	-	-	-	27.88 ± 2.49	-
Parafilm	3	-	0.52	1.92	7.08 ± 0.59	1.21 ± 2.07
Ethylene vinyl acetate (EVA) Foam	4	-	3.10 ± 1.01	0.35 ± 0.09	15.08 ± 3.50	0.99 ± 0.37

5.2.2 Puncture Test Results

Tabulated values for force (in Newtons) and extension (in mm) were obtained from the puncture testing on the different specimens. Because each specimen had a different thickness, the puncture force was normalized. The puncture force was normalized by diving the puncture force by the average thickness of all the trials. Subsequently, the normalized puncture force (in N/mm) was graphed against the extension for each trial. Using the maximum function in Excel, the maximum puncture force was determined for each material. The maximum puncture force represented the force necessary to rupture the specimen. The mean and standard deviation of the normalized puncture force across all the trials was determined for each material. This puncture analysis was completed on all the bovine and material samples. The data is recorded in Table 12 below, and the puncture graphs for each material can be seen in Appendix J.

Table 12. Maximum Puncture Force of the Bovine Samples and Synthetic Materials

Sample	Size (n)	Average Maximum Normalized Puncture Force ± SD (N/mm)
Bovine Colon	4	22.3 ± 7.1
Bovine Mesentery	4	6.14 ± 1.86
Bovine Small Intestine	3	26.5 ± 2.63
Green Foam	3	1.58 ± 0.23
OOMOO™	2	13.9 ± 2.3
PDMS (Sylgard)	1	238
Stove Silicone	3	21.0 ± 0.17
GLAD® Cling Wrap	3	171 ± 13.2
Sausage Casing Dry	3	30.8 ± 0.91
Sausage Casing Wet	3	46.5 ± 6.09
Parafilm	3	46.6 ± 2.26
ethylene vinyl acetate (EVA) foam	3	1.16 ± 0.031
Liquid Rubber	3	17.9 ± 3.2
Smooth-on: Ecoflex™ 00-20	2	9.82 ± 4.36
Smooth-on: Ecoflex™ 00-30	1	9.60
Smooth-on: Ecoflex™ 00-50	1	13.1
Smooth-on: Dragon Skin™ 10	2	22.5 ± 1.23
Smooth-on: Dragon Skin™ 20	2	26.8 ± 1.35
Smooth-on: Dragon Skin™ 30	1	37.0
Smooth-on: Dragon Skin™ FX Pro	1	14.9

5.2.3 Peel Test Results

Peel tests were completed to determine the adhesive strength of different materials in comparison with bovine samples that are possible condidates for the “glue” holding the organs together. These tests were completed using the Instron as described earlier, and the results of the tests were analyzed. With each test, the separation force (in Newton) and the extension of the material (mm) were recorded. The force was normalized by dividing the data with the contact area of the sample (multiplying the length and width of the sample). The curves of force versus extension were graphed. Then, the average peel strength of each material was determine by calculated the average force of the first peek and the average force of the sample. These values are reported, for each respective material, below in Table 13. Additional data and graphs from peel testing can be seen in Appendix K.

Table 13. Average Peel Force of the Bovine Samples and Adhesives

Sample	Sample Size (n)	Average Peel Force of the First Peek ± SD (N/mm2)	Average Peel Force of the Material ± SD (N/mm2)
Bovine Colon - Mesentery	3	1.7E-03 ± 1.3E-03	2.9E-03 ± 1.8E-03
Double-Sided Tape	3	1.4E-04 ± 2.1E-05	3.2E-04 ± 9.7E-05
Nano Grip Tape	3	2.4E-04 ± 5.7E-05	4.6E-04 ± 3.8E-05
Rubber Cement	4	1.4E-04 ± 2.1E-05	3.2E-04 ± 9.7E-05
Loctite® Spray	4	6.4E-05 ± 7.4E-05	5.5E-05 ± 2.6E-05
Spirit Gum	3	2.4E-05 ± 1.9E-06	1.8E-05 ± 4.1E-05
Hydrogel Patch	3	2.7E-04 ± 4.9E-05	4.4E-04 ± 1.3E-04
Hydrogel Collagen Patch	6	1.4E-04 ± 1.1E-04	1.2E-04 ± 9.8E-05
Gelatin - Glycerin	4	9.6E-05 ± 1.3E-04	8.8E-05 ± 1.3E-04
Hydrogel Liquid	4	8.6E-05 ± 8.4E-06	7.5E-05 ± 1.3E-05

5.3 Qualitative Testing

A preliminary qualitative test was performed to obtain the surgeons' opinions about what materials could be bio-realistic candidates. A survey, included in Appendix L, was given to 7 surgical residents and doctors (including the client Dr. Cataldo) at BIDMC. The purpose of this survey was to determine bio-realistic materials for different parts of the abdomen model; hence, the questions on the survey were about different materials and whether they would be appropriate to use for any of the organs or tissue.

5.4 Qualitative Test Results

The results from the preliminary qualitative test helped the team shorten the extensive material list developed based on background research. These results can also be found in Appendix L. The materials that were considered after this survey were Loctite® Spray (Loctite® 2235316), Rubber Cement (Elmer's® 231), sausage casing, Cling Wrap (GLAD® CXC-133B), green foam, parafilm, Smooth-On silicone (Dragon Skin™ & Ecoflex™), OOMOO™ 25 (Smooth-On SMOoomoo25), and PDMS (Sylgard 184). The Smooth-On silicone samples received the greatest recommendation since ~85% of the survey respondents (n=7) recommended that we use this material for the model. From this preliminary test, we were able to make a comprehensive list of possible material candidates to build the model.

5.5 Material Verification

The results from the quantitative and qualitative analysis were both used to determine the most bio-realistic material to use for each organ. The quantitative data was first analyzed using t-tests to compare the bovine and synthetic material test results. The material selection was narrowed down to those with tensile, puncture, and peel test results that were statistically equivalent to that of the bovine colon, mesentery, and small intestine samples. The remaining organ mechanical property values were obtained from literature and, therefore, did not have large enough sample sizes to run t-tests. Statistical equivalence was measured by conducting a t-test to compare the ultimate tensile strength, tensile strain, tangent modulus, load to failure, compliance, puncture force, and peel force of the samples. Any p-values that were above 0.05 were marked as statistically equivalent, as the data sets were not different enough to reject the null hypothesis. Tables of the calculated p-values and statistically equivalent materials can be found in Appendix M. This list of narrowed down materials was compared with the qualitative test results to determine the best material for each organ. The team used both quantitative and qualitative data to obtain the material that had similar mechanical properties and bio-realistic feel to fabricate the organs.

6.0 Final Design and Validation

6.1 Final Design

Section 4.4 described the alternative designs that the team evaluated to determine how the final model would be constructed. After analyzing each design as compared to the baseline Syndaver® model, the team decided to follow the first design alternative. The final design was as follows: each organ was manufactured individually and placed in an abdominal box trainer in their correct anatomical positions. The organs were supported by surrounding organs and held in place by a mixture of Elmer's® Glue, borax, and water, which was used as the retroperitoneum (refer to 6.1.2). The materials for each organ were selected by the p-values and qualitative data, as mentioned in Section 5.5. The protocols for fabricating each organ can be found in Appendix N. Figures 29 and 30 show the final model with the fabricated organs in place and with the model placed inside a box trainer.

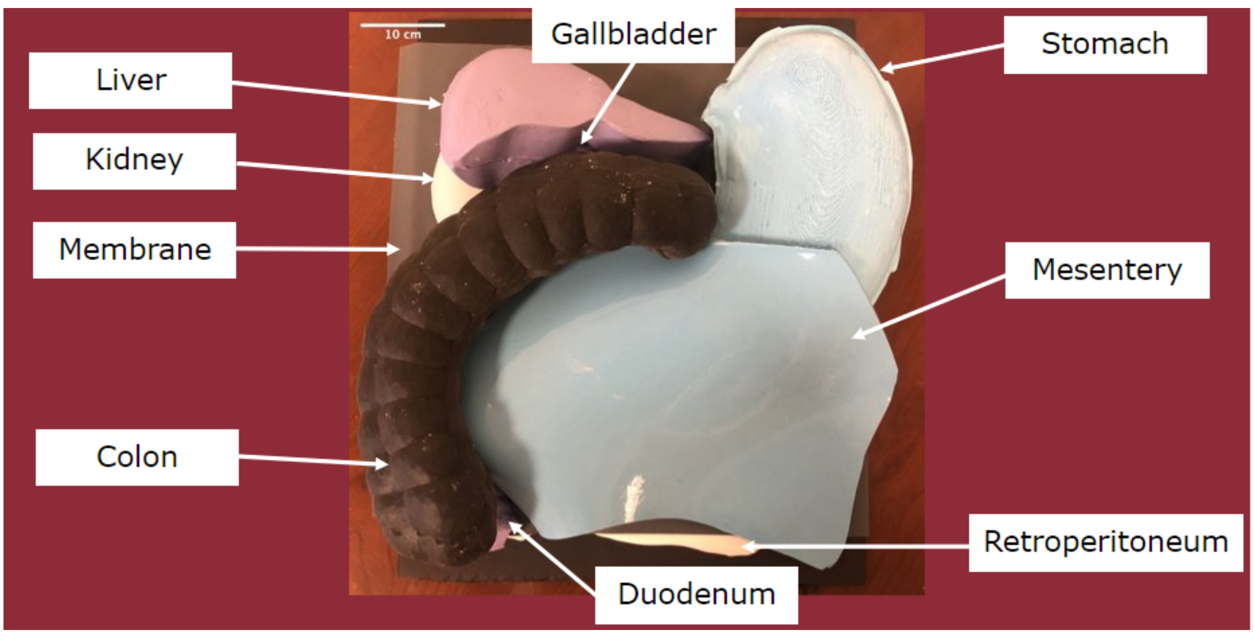

Figure 29: Final Model with Organs in place.

Figure 30: The Model Placed in a Box Trainer

6.1.1 Final Design of the Organs

The colon, shown in Figure 31, was fabricated by an external company, Stratasys Direct Manufacturing®. This company first used an STL editor to edit the part file. Then, they printed the colon in a silicone-like material called Agilus using a printing technique called PolyJet. The Agilus material has a shore hardness of 30 A, which is the closest hardness to the real colon. The Agilus material has UTS values (between 2.4 and 3.1 MPa), which were also the closest to the UTS values of the true colon (between 1.1 and 1.8 MPa). The size of the colon is 25 cm in length with a 3 cm inner diameter. Furthermore, the part was printed with the ridges of the transverse colon and the inside was hollow.

Figure 31: The Transverse Colon

The kidney, shown in Figure 32, was fabricated from Smooth-On Dragon Skin™ Series 10 silicone, which was selected based on the evaluation of tangent modulus resulting in a property value that aligns with the human kidney tangent modulus data found in literature. The liver, shown in Figure 33, was fabricated from Smooth-On OOMOO™ 25, as a preliminary model. Because there is lack of data in literature on the mechanical properties of the liver, and due to cost and time constraints, we were unable to obtain biological liver samples for testing. Future research needs to be performed to better understand the mechanical properties of the human liver.

Figure 32: The Right Kidney

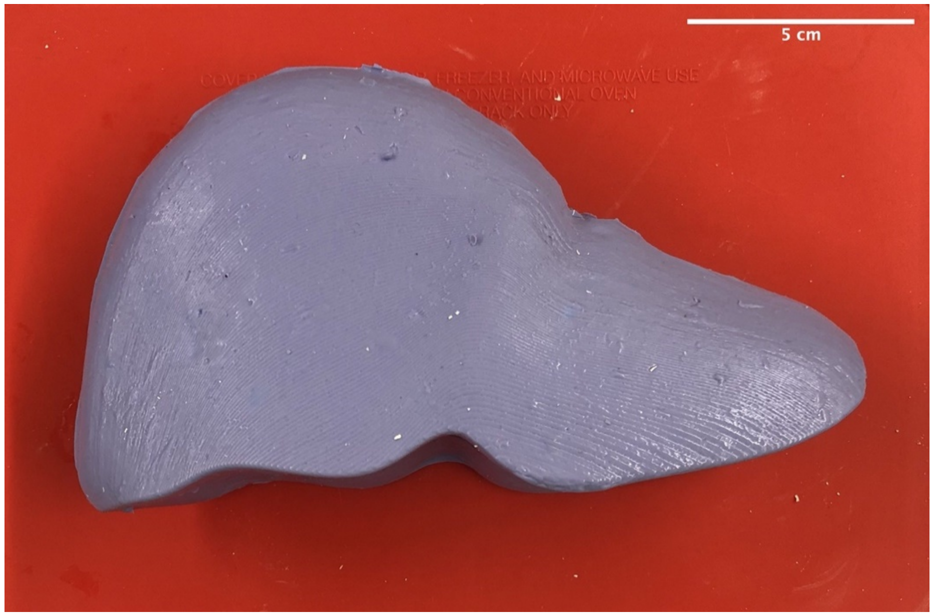

Figure 33: The Liver

The kidney and the liver were fabricated using inverse molding, as both of these organs are solid. An STL model of the respective organ was printed in two halves in polylactic acid (PLA). An alginate clay mixture was made by mixing equal parts by volume of alginate and water. The 3D printed respective organ halves were set in the alginate clay allowing the clay to cure with an inverse organ mold. Once the alginate was fully cured (approximately 8 minutes), the 3D prints were removed leaving a hollow imprint of the two organ halves. Next the Dragon Skin™ Series 10 silicone for the kidney, and the Smooth-On OOMOO™ 25 for the liver, were prepped by mixing equal parts by volume of part A and part B of each Smooth-On silicone together. Once the parts were homogenously mixed, the silicone was poured intolo the alginate inverse organ molds. The molds were left to cure for at least 4 hours. Once the silicone was fully cured, the halves were removed from the alginate. The kidney and liver halves were assembled by using more of their respective silicone with a brush-on technique. Both silicone molded organs were left to cure for at least 2 more hours.

The gallbladder, shown in Figure 34, was fabricated from Smooth-On Dragon Skin™ Series 20 silicone, which was selected based on the evaluation of tangent modulus resulting in a property value that aligns with the human gallbladder tangent modulus data found in literature. To fabricate the gallbladder, compression and inverse molding were used. First, an STL model of a human gallbladder was 3D printed in PLA. In a similar fashion to the kidney and liver, an alginate clay mixture was prepped, and half of the gallbladder 3D mold was pressed into the alginate clay before it cured. Once it cured, the gallbladder print was removed leaving a hollow gallbladder mold. Next, Smooth-On Dragon Skin™ Series 20 silicone was prepped by mixing equal parts by volume of part A and part B together. The silicone was poured into the inverse mold and the PLA gallbladder model was placed on top to compress the silicone. The cured alginate clay and rigid PLA gallbladder mold created a pocket for the silicone to cure in a hollow fashion. The silicone was left to cure for at least 4 hours. The same process was repeated for the other half of the gallbladder. Once the hollow silicone halves were cured, they were sealed together by using more Smooth-On Dragon Skin™ Series 20 by brushing the silicone around the edges of the halves and pressing them together.

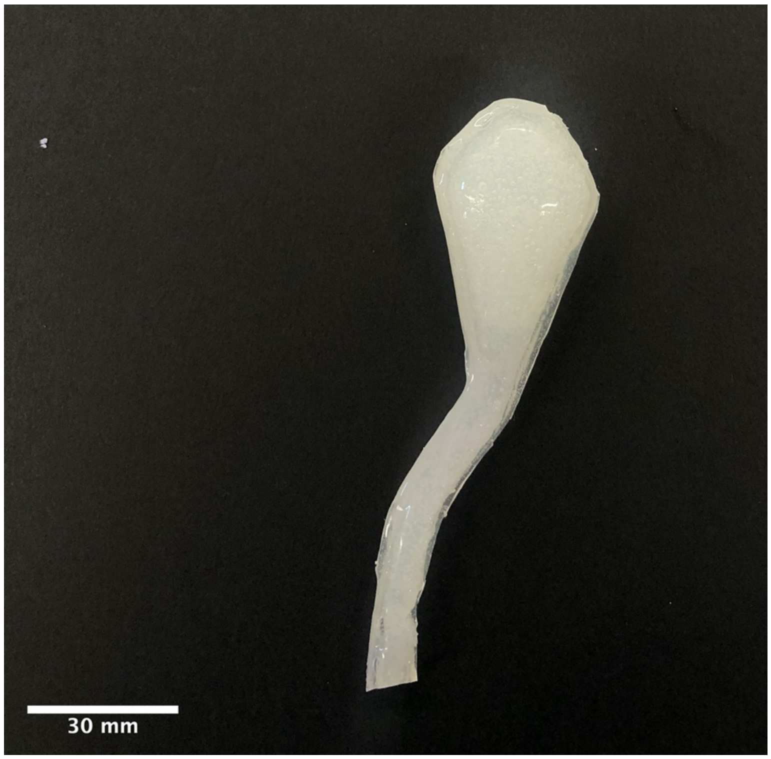

Figure 34: The Gallbladder

The stomach, shown below in Figure 35, was fabricated from Smooth-On OOMOO™ 25 silicone, which was selected based on the evaluation of ultimate tensile strength resulting in a property value that aligns with the human stomach ultimate tensile strength found in literature. The compression molding technique was also used. To fabricate the stomach, an STL model of the stomach was sliced in half and the two halves were printed. Next, the two STL stomach halves were scaled down and printed to create an inner mold. Equal parts of part A and B of the Smooth-On OOMOO™ 25 silicone were mixed together. Once the mixture was homogenous, a compression mold was fabricated by pouring the silicone into the two anatomically sized stomach halves. The two scaled down halves were then pressed on top of the silicone to compress the silicone between the anatomically sized printed molds and the scaled down printed molds. This process can be seen below in Figure 36. The molds were then cured for at least 4 hours. Once cured, the silicone stomach halves were sealed together by applying another layer of Smooth-On OOMOO™ 25 silicone around the edges of the halves and placing them on top of each other.

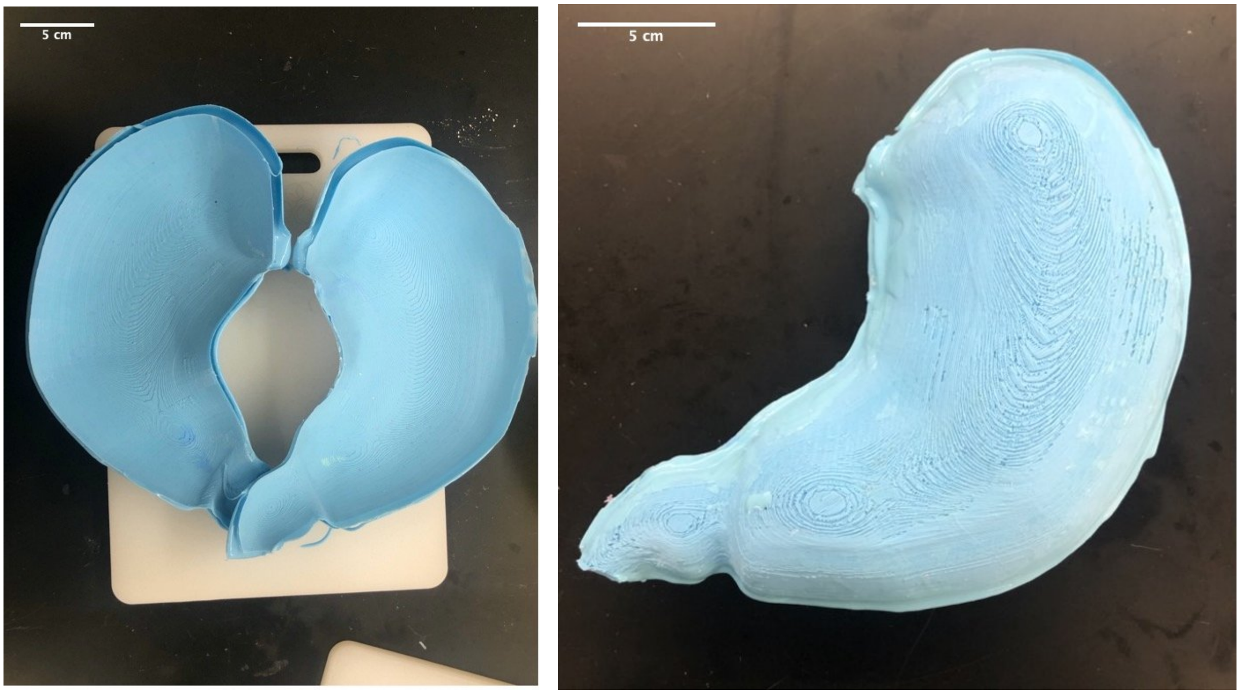

Figure 35: The Stomach Mold Halves (Left) & Final Stomach Mold (Right)

Figure 36: Stomach Compression Mold with Silicone In Between

The small intestine, shown in Figure 37, was fabricated from Smooth-On OOMOO™ 25 silicone. This material was chosen because the majority of data sets from the tensile, puncture, and peel tests were statistically equivalent to that of the bovine small intestine, as seen in Appendix M. Inverse and compression molding were used to make the small intestine. Similar to the previous organs, the 3D model was printed from the STL file of a human colon. This file was scaled down to the anatomical size of the small intestine. Then, the inverse mold was created by vertically submerging the 3D model in alginate. Once cured, equal parts of part A and B of the OOMOO® silicone were mixed together until homogenous. The mixture was poured into the inverse mold. The compression mold was made using paraffin wax. The wax was prepared ahead of time by melting it down to a liquid and then pouring it into a 3D model of a curved pipe with the same curvature and internal diameter of the small intestine. The wax was inserted into the silicone mixture to create a hollow mold. The mold cured for at least 4 hours and then was removed from the alginate. It was then sliced open at each end and put in an oven at 300 degrees Fahrenheit for around 5 minutes to melt the wax out.

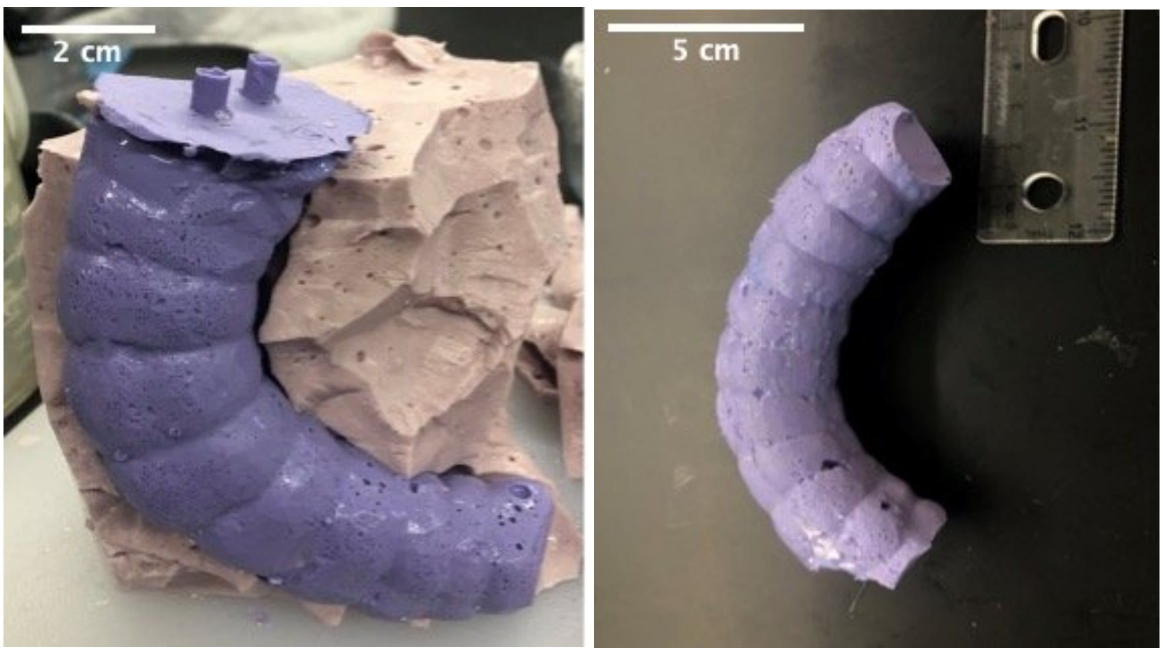

Figure 37: The Small Intestine (Left: In Alginate)

The mesentery, shown in Figure 38, was fabricated from Smooth-On OOMOO™ 25 silicone. This material was chosen because the data sets from the tensile, puncture, and peel tests were all statistically equivalent to that of the bovine mesentery, as seen in Appendix M. Inverse molding was used to make the mesentery. Equal parts of part A and B of the OOMOO™ silicone were mixed together. Once the mixture was homogenous, the silicone was poured into a box (which served as the inverse of the mesentery) with enough silicone to cover the bottom of the box. The sheet of silicone did not exceed 4 mm, to maintain its flexibility. The silicone cured for at least 4 hours and then was removed from the box. The sheet was cut and folded around the colon and surrounding organs to resemble mesentery in the model.

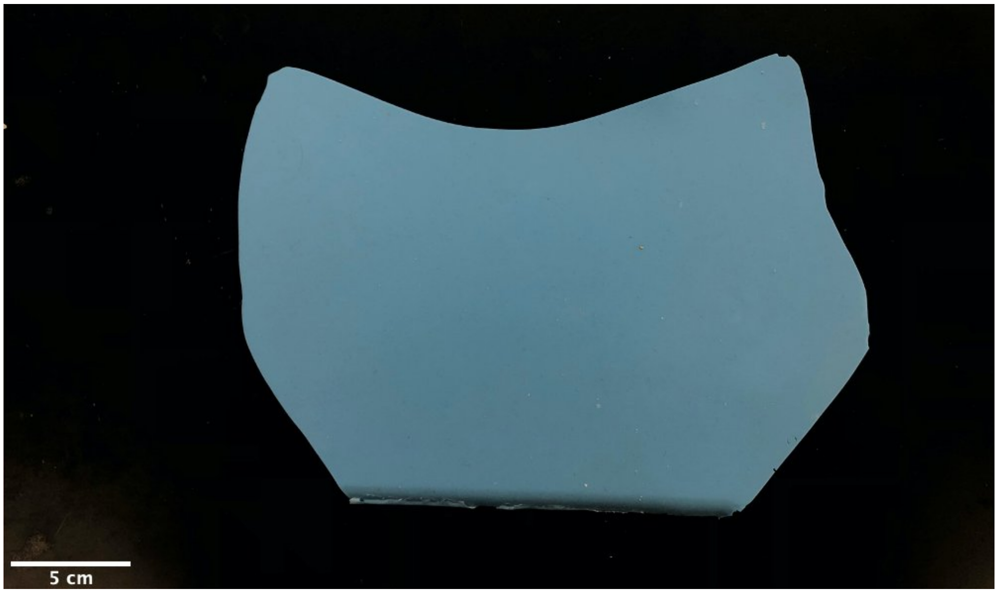

Figure 38: The Mesentery

The retroperitoneum was made from slime material. The slime material was thought to simulate the gel-like substance in which the organs were suspended in. Slime was made with Elmer's® Liquid School Glue (catalog number: E304NR), Milliard® Borax Powder (catalog number: B00HLROB6E), and water. Glue and water were combined in a 1:1 ratio (4 ounces), and a borax mixture (1 teaspoon of borax and 4 ounces of water) was added into the glue mixture to produce the slime. In the future, a larger amount of slime will be created since only a small sample was made for this iteration of the model**.** The retroperitoneum will connect to the peritoneum membrane (McMaster-Carr® silicone rubber sheet) and mesentery with an adhesive material in between. Collectively, this component along with the peritoneum, adhesive, and mesentery will represent the all the fat tissue surrounding the organs.

6.1.2 Final Design of the Box Trainer

The team fabricated a box trainer, as shown in Figure 39, with dimensions of 29.2 cm x 36.8 cm x 27.9 cm, using 3 acrylic sheets, 1 translucent plastic drawer placemat, and 1 plastic black ribbed shelf liner. These items were adhered together with super glue, creating a box with one side open. A removable, opaque, black plastic sheet was fixed to the box trainer using Velcro to simulate operation inside a human abdominal cavity. Lastly, 6, 1-cm holes were placed in the placemat that covered the box trainer; the holes serve as insertion points for surgical trocars. The material list for the box trainer is described in detail in Appendix O.

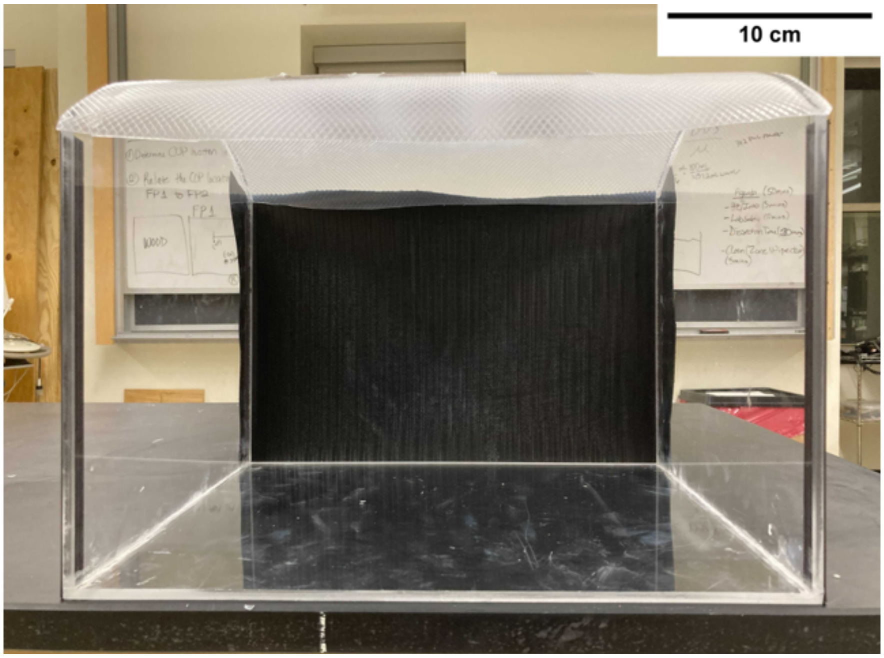

Figure 39: The Front View of the Box Trainer

6.2 Validation

Once the final design of the model was assembled, the team needed to assess how well it met the objectives. This was conducted through validation surveys with BIDMC surgeons and then analyzing those results. The survey questions and results can be found in Appendix P.

6.2.1 Validation Survey

The final validation test was completed once the model was built. The model containing the different organs and fat tissue was brought to BIDMC for evaluation by residents and surgeons. A survey was administered to 6 residents and surgeons (including the client Dr. Cataldo). Through the survey questions, the residents and surgeons were able to evaluate the effectiveness of the model based on our design objectives. The surgeons used laparoscopic tools to interact with the organs/tissue, and from their surgical experiences, they were able to rate how accurate the model is using a 7-point scale. The parts of the model that are not similar will have to be re-evaluated and re-designed in the future.

6.2.2 Analysis of Validation Survey

The validation survey yielded important results for future versions of the design. The surgeons/residents were asked to interact with the model using the laparoscopic tools and rate the model in terms of bio-realistic properties of the organs on a scale of 1 (least bio-realistic) to 7 (most bio-realistic). The average score was a 2.5 out of 7 (n=6). According to the surgeons, the organs constructed were too stiff, so they will have to be made with softer materials in the future. The trainer will be able to hold a significantly higher educational value to the residents after the components are made to be more bio-realistic by reducing the stiffness of the organs. The final design received an average rating of 4 out of 7 (n=6) for how visually realistic the model is. This aspect will be improved by paying more attention to the retroperitoneum, “glue”, and mesentery components surrounding all the organs. The surgeons were explaining that when they perform operations, they use the laparoscopic tools to navigate around all this surrounding tissue/fat before reaching the abdominal organs. It is important that our model simulates this phenomenon, so residents can become proficient with this skill and learn how to avoid mistakes such as harming other organs. The residents were also asked to rate the model in terms of how easy to use the model was on a scale of 1 (least easy) to 7 (most easy). The average score for ease of use was a 5.5 out of 7 (n=6), so the model adequately met this criterion. Finally, while the trainer was under the $800 cost limit, we still need to consider how to lower the cost of the replaceable parts to increase the reusability of the model. Moreover, once the model is modified, additional validation studies testing the educational value of the model can be completed with the residents over time.

6.3 Industry Standards

A college must demonstrate appropriate performance in the standards and elements from the Function and Structure of a Medical School to be accredited by the Liaison Committee on Medical Education (LCME). The requirements ensure graduated medical students demonstrate professional skills that are essential for entering the next stage of training. The Function and Structure of Medical School is organized into 12 standards. The use of our model falls under Standard 7: Curricular Content and Standard 9: Teaching, Supervision, Assessment, and Student and Patient Safety. Standard 7 mandates that students must develop critical judgment and problem-solving skills through the curriculum. Standard 9 requires realistic, hands-on experience for students to acquire proficient laparoscopic surgical skills. The model can be used to simulate different scenarios in the operation room to practice and refine the user's skills [79].

The phantom allows for repetitive practice as a recursive adjunct to surgical training in the operating room. The model serves as an inanimate bio-realistic, reusable laparoscopic surgical training device that accelerates the learning curve for residents. Users can practice on the model without negative repercussions. The phantom also addresses ethical concerns regarding training on a human cadaver.

ISO 527 and ISO 11339 serve as the framework to investigate the mechanical characteristics of materials. ISO 527 series are used to determine the tensile properties of plastics and plastic composites under defined environments. The tensile strength, tensile modulus, and tensile stress-strain relationship are assessed through the testing methods. Different materials require specific testing procedures, which are detailed in the series. The methods are suitable for rigid/semi-rigid thermoplastics, rigid/semi-rigid thermosets, fibre-reinforced thermoplastic composites, fibre-reinforced thermoset composites, and thermotropic liquid crystal polymers. These groups include materials used to fabricate the model [80]. For the puncture properties of materials when using a pointed-tip object, there are no industry standards to measure the resistant force. The peel strength between flexible adherends is tested according to ISO 11339. The standard specifies T-peel tests for measuring the bonded force of adhesives. This could be used for both metal and flexible materials [81].

6.4 Impact Analysis

The following sections discuss the impact and influence of our surgical trainer as it relates to the economy, environment, society, policy, ethics, health & safety, manufacturability, and sustainability.

6.4.1 Economics

The principal economic benefit of a bio-realistic, cost-effective and reusable laparoscopic trainer is that it helps improve healthcare delivery by making it easier and more cost-effective to train colorectal surgeons. Chapter 2 expounds on the importance of simulation training for improving laparoscopic skills and on the importance of repetitive practice for enhancing residents' psychomotor skills and hand-eye coordination. By adopting use of the team's surgical model as an adjunct to colorectal surgical training, residency programs will be able to train a greater number of surgeons over shorter periods of time. This would effectively reduce the cost of training colorectal surgeons, though a comprehensive study would have to be conducted to assess cost-savings of implementing the team's surgical trainer in a residency training program. A bill of materials can be found in Appendix O.

6.4.2 Environmental Impact

Because the organs within the model are made from silicone, this could impact the environment. If silicone enters the environment as waste, it does not break down for nearly centuries [82]. However, in understanding how this could be detrimental to the environment, potential solutions have been considered. First, our model is designed to be reusable (it is not single-use), so there would not be silicone waste with every use of our model. Next, silicone is a material that has the potential to be recycled. However, because the average human often mis-labels polyurethane as silicone, silicone is not accepted as a recyclable from most community recycling companies. Nevertheless, there are specialized recycling companies that allow you to ship silicone to their facilities, and they will handle the recycling process. Silicone can be recycled multiple times, but it needs to go through a specialized process that these companies handle. It is cost-effective to ship silicone to these companies in bulk. When we begin mass manufacturing this surgical trainer we could provide shipping materials to the companies that order from us to send their used silicone back to us. Then we could send a bulk shipment of used silicone to a specialized recycling company to avoid silicone from entering the environment as much as possible.

6.4.3 Societal Influence

The model will allow for more efficient training of laparoscopic surgery. The surgical phantom will provide a training tool that is more bio-realistic and affordable than the current models on the market. The long-term goal of the project aims to train surgeons in low-income countries in a more cost-effective way. After upgrading the laparoscopic rooms, hospitals in the United States and other Western countries often donate used laparoscopic equipment to hospitals in low-income countries. However, the equipment lays unused as there is no formal training for surgeons there. Our model would bridge the gap and serve as a training tool for surgeons in low-income countries.

6.4.4 Political Ramifications

There are no political ramifications surrounding the design, development, and manufacturing of this surgical trainer. This product would instill great impact on a global scale and would change the scope of surgical training. Training in the operating room would be reduced to observation only, rather than learning and performing surgical procedures on a patient for the first time. Due to the reusability and replaceability of the surgical trainer, medical institutions would be able to readily obtain parts for the trainer and allow residents to use them recursively. Over time when the parts do need to be replaced, medical institutions can order and replace individual parts, rather than purchasing an entirely new model. Due to the low-cost criteria that our model meets, this product will meet end-user needs across the world including in low-income countries. This in turn will allow low-income countries to have the necessary resources to train proficient surgeons, which is a current unresolved medical challenge. This product would not have any effects (negative or positive) on the culture of other countries. This surgical training model will serve as a platform for training residents, without risking patients' health and safety.

6.4.5 Ethical Concerns

During testing, the team utilized bovine tissue obtained from a cow abdomen to collect baseline values for the organs' material properties. This arises ethical concerns because the cows must be slaughtered to be used for this project. The team attempted to reduce the ethical concerns by obtaining bovine specimen from cows that were already scheduled to be slaughtered for the facility's use.

In the future, the model organs will be made from the CT scans of one patient who represents an average human. This would help make the organs have a more appropriate size relative to each other, and the different parts would fit together more precisely. It will be important to maintain patient anonymity when using these CT scans.

6.4.6 Health and Safety Issues

This product does not have any health and safety issues, in fact with this surgical trainer, health and safety risks in colorectal surgical training are reduced. Risks are reduced because rather than having residents train in the operating room on a live patient case, they would use this model as a transition into the operating room. Repetitive skill training with this model should reduce mistakes made in the operating room, reducing patient risk. The current design does not include materials that would be harmful for the trainees. The organs would be pre-made and sent to medical institutions, so there would be a minimal set-up process. Because the model is used outside of the operating room there is no process for sterilizing the model.

6.4.7 Manufacturability

This surgical phantom trainer has a lot of potential to be manufactured in the future, as that is the long-term goal of this project in collaborating with BIDMC. The team manufactured the colon from an external company, however the results were not as expected. The colon was 3D printed, however, currently, there is no material with a soft enough durometer that can be 3D printed. However, various molding techniques with bio-realistic materials can be used to increase manufacturability. Techniques such as injection and rotational molding can be applied to decrease production time and increase ease of production, making the mold much easier to take from a small to large scale market. In working with BIDMC, future teams hope to create a design that can be quickly and easily manufactured for training hospitals, with inexpensive replacement parts available in large quantities.

6.4.8 Sustainability

Silicone and polymers are the main components used to fabricate the organs of the model. The organs are placed in an acrylic box trainer to simulate a realistic laparoscopic experience for users. The trainer also serves as storage. All materials are generally inexpensive, durable, and long-lasting under minimal stress. The phantom is highly sustainable as individual parts are affordable and resilient, helping to minimize the waste products created by the use of the model. The phantom is intended to last through years of use and requires only small, commercially accessible replacement parts. Additionally, the model requires no external energy to operate.

7.0 Discussion

In this section, we will analyze the final design of the surgical phantom among each of the five design objectives: bio-realistic, cost-effective, reusability, easy to use, and educational. Table 14 below visually shows the results for each objectives with a big check mark if the objective has been met, and a small check mark if the objective has been partially met. Each of these results are discussed and justified in sections 7.1-7.5.

Table 14. Summary of Objectives

Objectives	**Results**
Bio-Realistic	☑
Cost-Effective	☑
Reusability	☑
Easy to Use	☑
Educational	☑

7.1 Analysis of Bio-realistic Objective

As part of the bio-realistic objective, the organ to model ratio was intended to be 1:1, and the model was supposed to mimic mechanical properties (puncture, tensile, and peel forces) and biofluids. The organ to model ratio was 1:1, however the organs were not the appropriate size relative to each other. For example, the stomach was very large compared to the liver and in the future, the organ sizes would have to be adjusted. From the final validation survey, we learned from the surgeons that the model is currently not accurate in terms of biomechanical properties (average rating of 2.5 out of 7 for biomechanical accurateness). Most of the organs were constructed to be too stiff, and the organs would need to be modified to be softer. The only organ that was constructed with the appropriate stiffness was the kidney since it is a naturally stiff organ. Due to time constraints, we were unable to incorporate biofluids in this model, and the next iteration would include biofluids, such as bile or blood, with the organs.

7.2 Analysis of Cost-effective Objective

For the cost-effective objective, the model should be affordable, yet made from materials that recapitulate human tissue. The entire model must be less than $800.00 with individual replacement parts marked at $20.00 or less. As shown in Table 15 (and further broken down in Appendix O), this surgical trainer meets the total cost specification.

Table 15. Surgical Trainer Cost-Break Down

Material	**Unit Price**	**Quantity per Model**	**Price**
Smooth-On Silicone (Organ Fabrication)	$32.21	2	$64.42
Colon (Stratasys® 3D Manufacturing)	$578	1	$578.00
McMaster Carr® Sheet (High Temperature Silicone Rubber Sheet, Ultra-Thin 10A Durometer)	$30.70	1	$30.70
Elmer's® Foam Boards	$2.05	1	$2.05
Box Trainer	$45.00	1	$45.00
Loctite® Spray	$6.99 (estimate)	1	$6.99 (estimate)
Retroperitoneum Fabrication	$1.31	5	$6.55 (estimate)
Total			**$733.71**

The breakdown in the table highlights the materials used and calculate the total cost for one model at $733.71. A significant portion of the cost was due to 3D printing the colon with a third party company called Stratasys®, which cost $578 for just the transverse colon. However, we do not believe 3D printing the colon is a viable option to meet our objectives at this time because 3D printers do not currently support soft materials that meet the mechanical properties of human tissue. As the technology of 3D printers continues to advance, there is potential to use 3D printers in future iterations of the model. The individual replacement parts cost specification has also been met. For the Smooth-On Silicone material that was used for fabricating the small intestine, liver, stomach, gallbladder, kidney, and mesentery averages to about $10.73 per organ. In manufacturing individual parts, the organs could be fabricated from silicone and individually shipped at an affordable cost.

7.3 Analysis of Reusability Objective

For reusability objective, organs of the model should be reusable from 3 to 4 times and different components should be replaceable individually. The model needs to satisfy these requirements to provide users with the same experience while practicing. The first specification requires more testing to determine how many times the organs can be operated on. This also varies depending on how intensive the model is used. The second specification is met by the model as the design of the model was chosen to design allows the organs to be replaced individually.

7.4 Analysis of Easy to Use Objective

As mentioned previously in Section 6.3, the model was rated on average 5.5 out of 7 (n=6) for easy to use by BIDMC surgeons. The surgeons stated that the model required very minimal learning time before being able to use it without direction. This is because the set-up and appearance are very similar to human abdominal surgery, with laparoscopic tools inserted through trocars and the organs in anatomical positions. The specification for this objective is that the model requires under 30 minutes of prior training time. This objective was accomplished because the average training time for the surgeons during the validation studies did not exceed this time limit. However, more extensive studies must be done to get a more accurate idea of how long the prior training time is for the model and if this varies based on surgical experience.

7.5 Analysis of Educational Objective

The model is designed to offer a platform for recursive practice and bridge the transition to the operating room for colorectal surgeons. Since the model has not been fully developed, it is difficult to assess the effects of its implementation for surgical training. An assessment of the educational value of this model would likely involve a randomized, double-blind, controlled longitudinal study involving multiple residency programs and following trainees at several stages of their careers.

7.6 Limitations

The current model of the team's laparoscopic trainer has several limitations. First, in validating the surgical phantom, the team was limited by the size and scope of the surgeon and resident pool from which the survey was conducted. In scope, the validation studies occurred only at Beth Israel Deaconess Medical Center. Due to the COVID-19 pandemic and travel restrictions, as well as the time constraint of the project, the team was unable to receive feedback from other hospitals. In addition, we only surveyed a small pool of surgeons and residents at BIDMC, limiting the sample size of the results. Future studies should incorporate surgeons and residents beyond BIDMC, and surveys should be conducted with a larger sample population.

Based on validation studies conducted at Beth Israel Deaconess Medical Center, the abdominal model is not very bio-realistic. Trainees ranked the model with an average score of 2.5 on a Likert scale of 1 to 7. The trainees opined that the organs were too dense and did not adequately simulate the separation of organs using laparoscopic instruments. Despite this drawback, the trainees expressed excitement about the potential of the team's trainer to displace current models and become the new gold standard. Additionally, the team noted that the colon — the only organ manufactured by an outside vendor—was the most expensive component, accounting for 79% of the total cost. Future work will focus on fabricating the colon in-house to reduce costs and make the organs more bio-realistic.

8.0 Conclusions and Recommendations

8.1 Conclusion

Our results prove that there is a need for a bio-realistic, cost-effective, reusable laparoscopic surgical trainer. Our model is a promising development that supports this need. The Bio-Realistic Surgical Phantom offers a platform for detail-oriented training of surgical techniques without risking patient health at a low cost. While this surgical trainer is composed of inanimate materials, it allows trainees to understand the anatomy within the RUQ, offers a platform for making mistakes and learning from them, and having the ability to repetitively practice techniques until the trainee feels confident. While this iteration of the surgical trainer has met some of the objectives and needs of the design, there is still room for improvement, which can be tackled with more time and resources, which will be discussed in the recommendations section of this chapter.

8.2 Recommendations

The team has many propositions for future iterations of the surgical trainer that may be conducted by future teams. In order to meet the objectives identified for this project, more bio-realistic organs must be made. This can be accomplished by scaling up the 3D model of the liver to its anatomical size so it meets the 1:1 model to human ratio specification. Another way to improve anatomical similarity of all the organs is to use CT scans to create the 3D prints so the organs are all from one human. Also, the retroperitoneum must be extended to encompass all of the organs in the abdomen, as it is currently just covering the base. This will allow all of the organs to sit on different planes of the box trainer more easily, instead of laying flay. The mesentery was also lacking in quantity and anatomical placement. A thinner sheet of silicone or another similar material would be more ideal for the mesentery, so it can be manipulated into folds that go around the intestines. The colon must be fabricated in another fashion than 3D printing, as the team discovered that was not a cost-effective or beneficial technique. This process was expensive and did not produce a bio-realistic organ. The molding method used for the small intestine can be applied to the colon as a potential means of production. The major bio-realistic component that is missing from this model is the glue between the organs. Human organs have an adhesive liquid between them, called the interstitium. By adding this between the phantom organs, it would provide a more bio-realistic and educational experience to the surgical trainees.

Another recommendation to improve the bio-realistic properties of the model is to conduct mechanical property tests again with organ samples that are more like human tissue. Porcine or mouse tissue have more biomechanical and anatomical similarities to human abdominal organs and would produce more reliable results than the bovine tissue. This would allow synthetic materials with more bio-realistic properties to be chosen for the organs.

Due to time constraints, the team was unable to conduct long-term studies on the easy to use, educational and reusability aspects of the training model. Once the model is improved upon, it is recommended that it be given to surgeons of varying levels to assess these objectives. An outline of such a study is described in section 7.5. Studies could be conducted on how long the prior training time is for interns, residents, and attendings, to make sure the model is easy to use. Also, long term educational studies should be conducted to see if surgical trainees using the surgical trainer are improving upon their skills and how well it translates into success in the operating room. Finally, reusability studies should be held to see how long the organ materials and glue last before degrading and requiring replacement. Tests such as repetitive peeling, poking, or suturing could be done to assess this.

The hope is that eventually future iterations will more closely resemble the team's alternative design 3, incorporating bodily fluids, haptic feedback, and a cardiovascular system. This model is meant to have a bio-realistic environment, including temperature, color, and adding gas to inflate the abdomen. It is also recommended to extend the trainer to the entire abdomen, rather than just the right upper quadrant. These components are vital to providing surgeons with an effective model that can prepare them for operating on a human abdomen. Future iterations could also include diseased states of certain organs, as they have different appearances and properties.

A long-term goal the team set out for this project, as it is continuing to be improved, is introducing it to surgeons in third world countries. Often, hospitals receive old surgical equipment and training tools from developed countries, however they do not have the expertise or facilities to put it into practice. By maintaining the surgical training model's low cost and ease of use, it can be utilized in these places to improve training programs and patient outcomes no matter the setting.

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Appendix

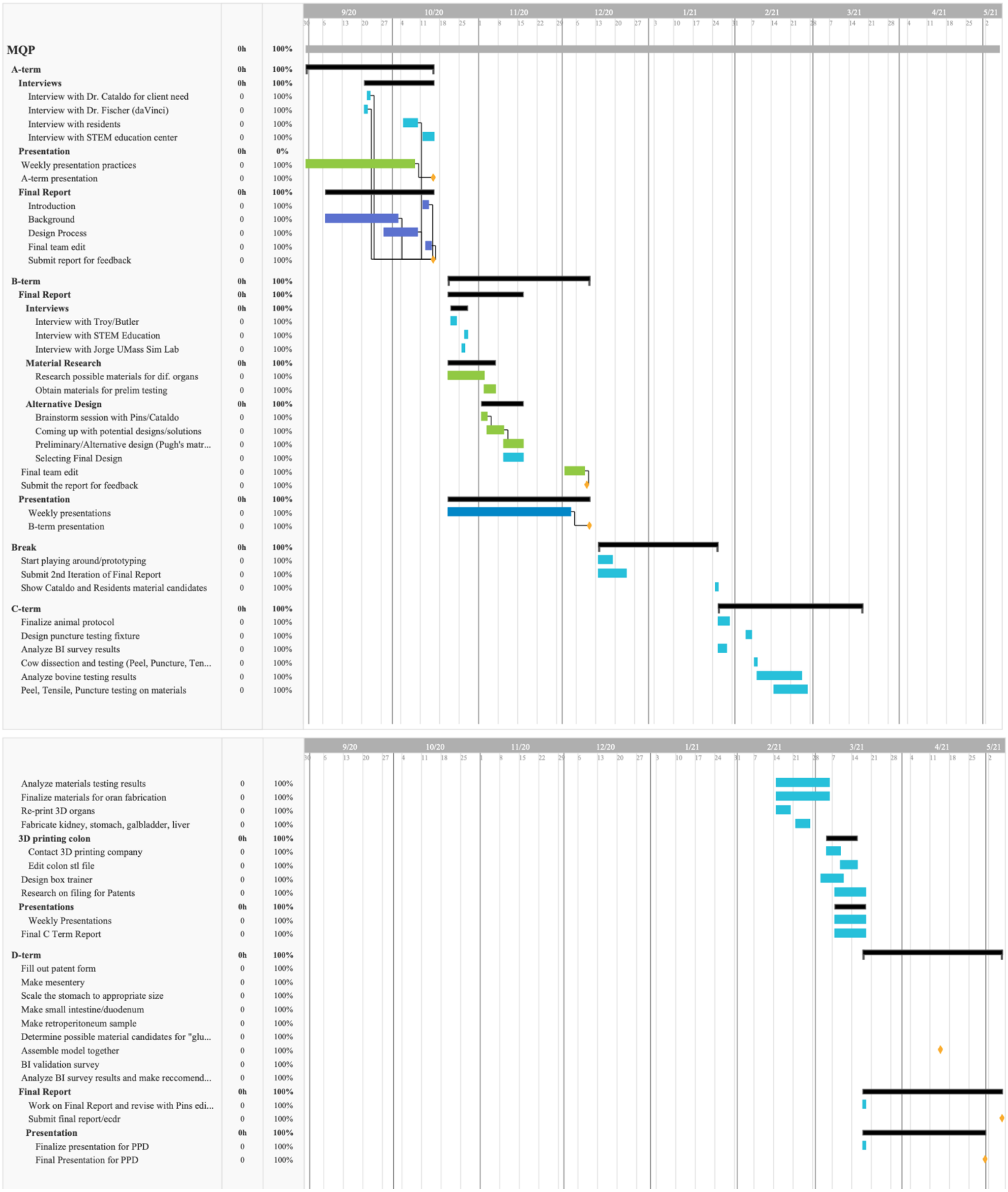
Appendix A: User Stakeholder Objective Ranking

	A	B	C	D	E	F	G	H	Totals
Bio-realistic	1	4	3	3	2	1	3	2	2.3
Easy to Use	2	1	1	1	3	3	2	1	1.7
Educational	3	2	2	2	1	2	1	3	2.0
Cost-Effective	4	5	5	5	5	5	5	4	4.7
Reusability	5	3	4	4	4	4	4	5	4.1

Appendix B: Designer Stakeholder Objective Ranking

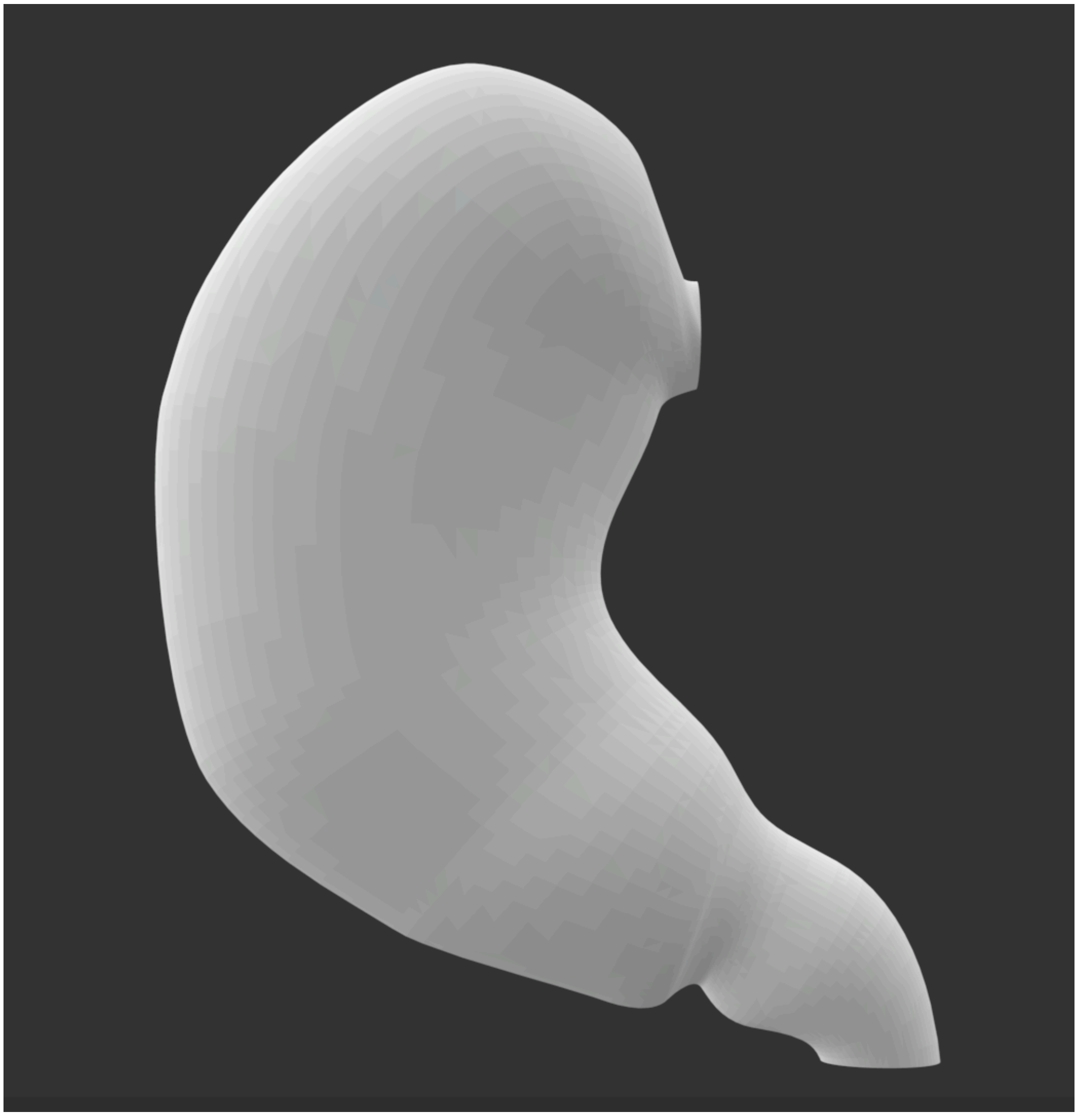
	Shanna	Parima	Izzy	Mark	Amy	Totals
Bio-realistic	3	2	2	4	1	2.4
Easy to Use	4	1	5	1	5	3.2
Educational	1	3	1	3	2	2.0
Cost Effective	2	4	3	2	3	2.8
Reusability	5	5	4	5	4	4.6

Appendix C: Gantt Chart

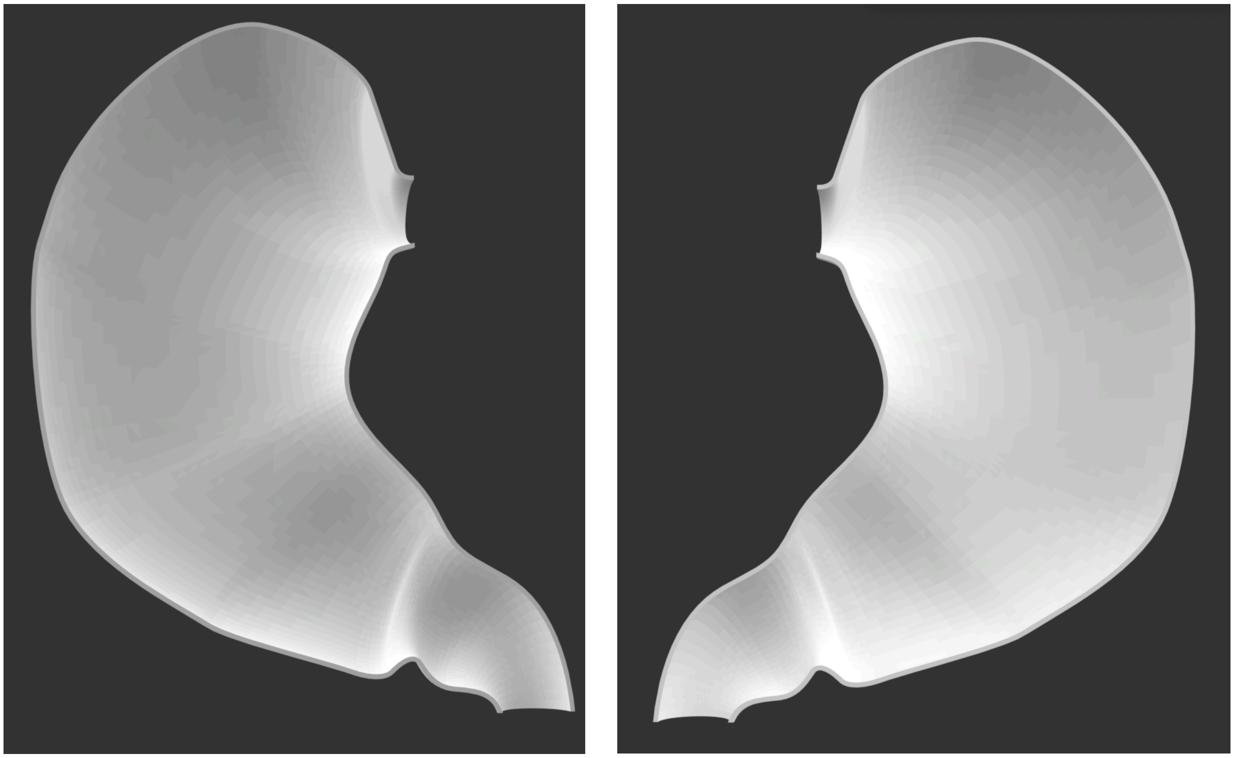


Appendix D: Organ CAD Drawings

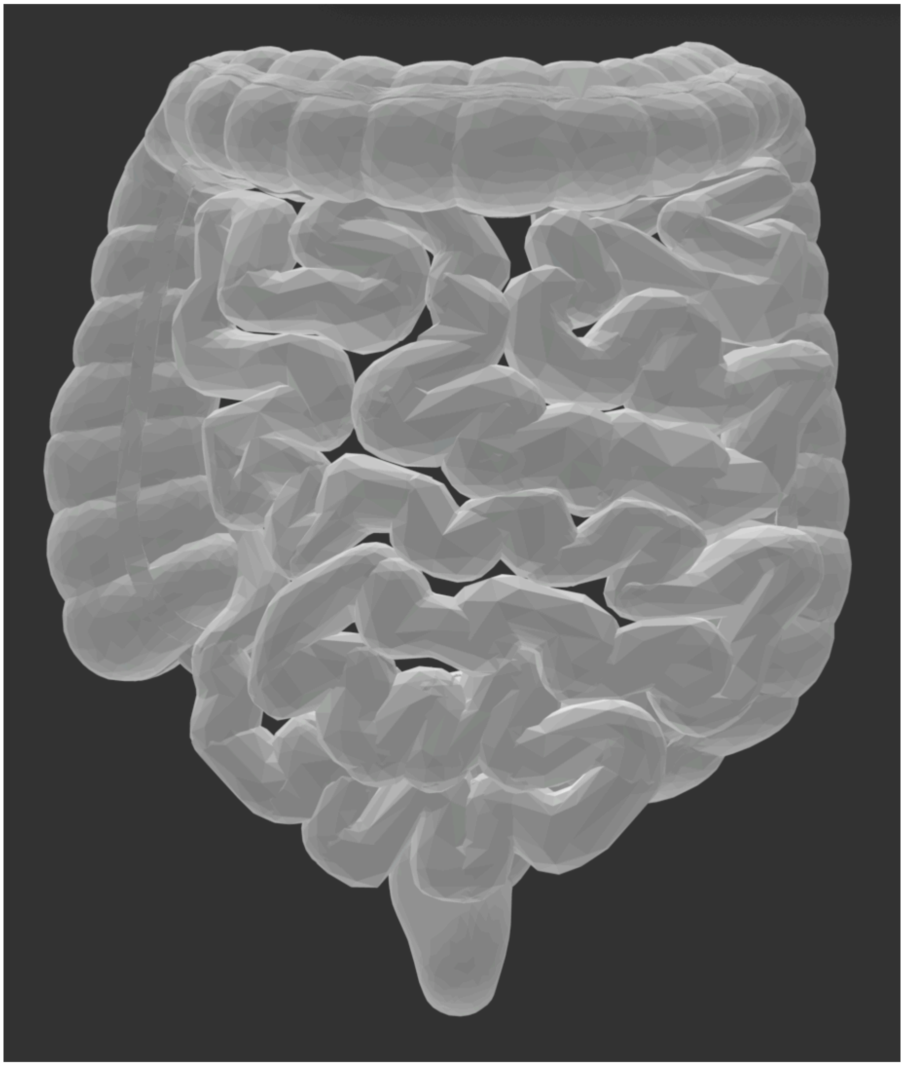
Stomach



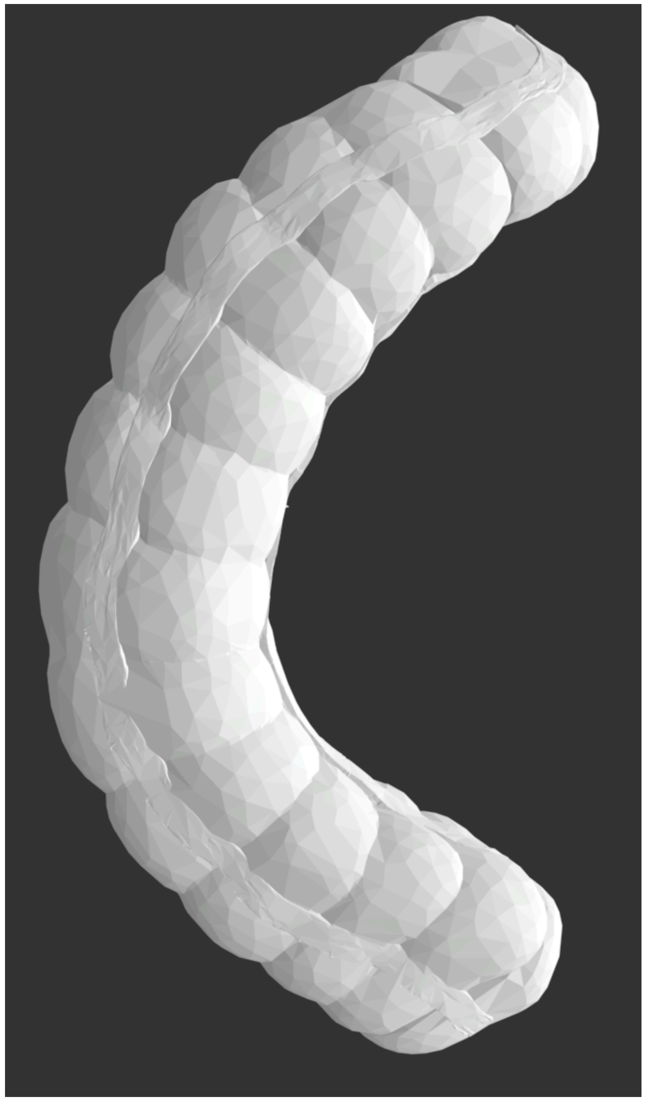
Sliced Stomach Halves



Large and Small Intestines



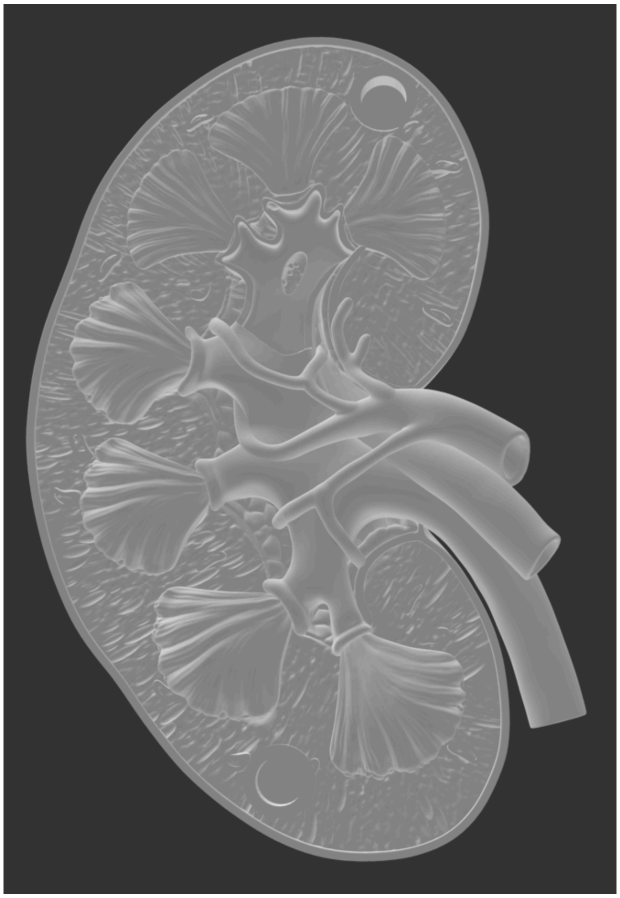
Sliced Small Intestine



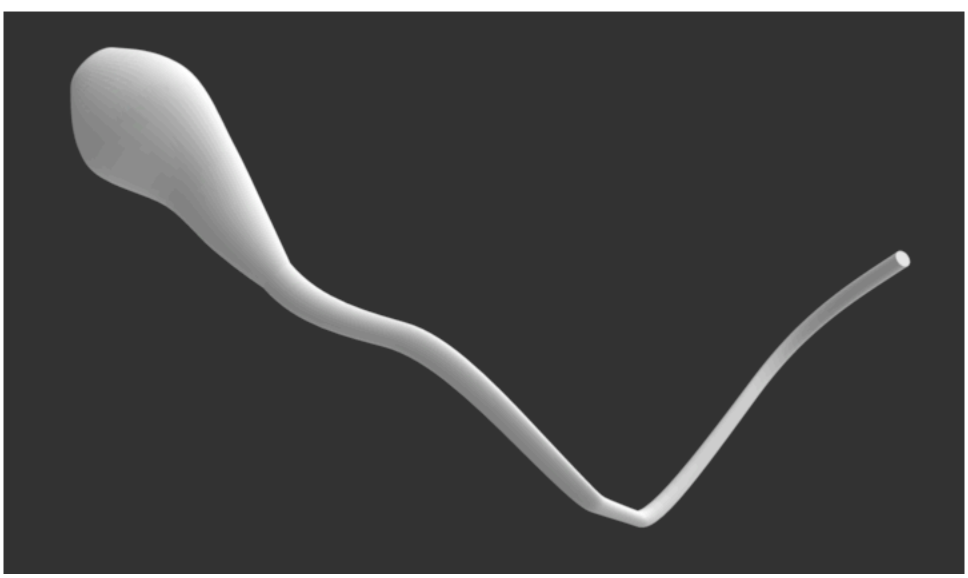
Liver

Right Kidney

Sliced Right Kidney Halves



Gallbladder



Appendix E: Synthetic Material and Animal Tissue Testing Protocol

Specimen: Bovine GI Tract
Source: The Blood Farm Groton, MA

Instron Tests:
Tensile Testing (ASTM 412-16)
Puncture Testing (ASTM D4833)
Peel Testing (ASTM D903)

Preparation

Tasks to do before Test day:

1. Design and develop puncture fixtures.
2. Call Bloodfarm to determine approximate size Styrofoam™ cooler we need.
3. Call Bloodfarm on February 7th/8th to let them know we are picking up on the 10th.
4. Notify Lisa / anyone else on campus that needs to know we are working with animal samples.

Materials:

- Cutting tools
  - Tweezers
  - Forceps
  - Curved dissection scissors
  - Surgical dissection scissors (blunt)
  - Scalpel
- Cleaning products
  - Cleaning sprays (available in Goddard Hall- GH)
- Testing
  - Instron 5544
  - Wrench
  - Sandpaper
  - Specimen covering paper
  - Saline
  - Glass container
- Other materials
  - Cutting boards (available in GH)
  - Lab gloves
  - Styrofoam™ box and ice for storing purposes

- 50-gallon trash bags

Obtaining Sample:

- Animal samples collection guidelines.
- Fresh tissues should be placed in a sterile, leak proof container, and maintained at a cool temperature (i.e. ice pack in Styrofoam™ box large enough for pig—at least a few feet).
- Samples should be stored in a fridge at 4 ºC as soon as possible after collection.

Prepping Samples:

1. Cut samples in specific shapes for each test
    a. Circle/square, 5 cm diameter for puncture apparatus
    b. Rectangular, 2.5 cm x 15 cm for peel/ tensile test
2. Obtain 3 axial and 3 transverse samples per organ if possible
    a. Organs: colon, stomach, liver, kidney, gallbladder, duodenum/small intestine, mesentery, peritoneum, retroperitoneum

Testing Preparation

Tests to Perform:

We will perform three tests using ASTM standards and the Instron 5544: Tensile Test, Puncture Test, and Peel Test.

Bluehill Setup: (this will be used for all tests)

1. Test
2. Browse tensile test
3. Method
    a. Specimen > Geometry > Rectangular
    b. Control > Pre-Test > Do we want to add a pre-load?
    c. Control > test > Extension at 150 mm/min
    d. Control > End of Test > Criteria 1 - Rate of load / sensitivity (%) = 40
    e. Control > End of Test > Criteria 2 – Load / 1900 N (since load cell of Instron 5544 can only withstand 2000 N)
    f. Control > Data > can set how often we want to take data
    g. Control > Strain > Extension
    h. Calculations > Set up> drag over what we need – max load, break, modulus yield
    i. Results > drag over what we need
    j. Graphs (load/extension vs time, stress vs strain)
    k. Raw Data > time, extension, load, tensile strain, tensile stress

l. Reports > Save
m. Export Results > .CSV save
n. Export Raw Data > .CSV save
o. And include additional specimen results- length thickness and width

4. Running Test
    a. Move cross head down, load sample, set mechanical stops
    b. Add pre-load, zero extension
    c. Enter values for specimen label, geometry, thickness,
    d. width, and length
    e. Add sample description
    f. Put up safety shield
    g. Run test
    h. Finish > Finish Sample > Save
    i. Start another sample

Tensile Testing

<u>Standard:</u> ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension

<u>Method:</u>

1. Place specimen in grips of Instron and tighten grips as much as possible
2. Set the rate of separation to 150 ± 50 mm/min (20 ± 2 in./min)
3. Set up Bluehill (see "Bluehill Setup" above)
4. Record and calculate average ultimate tensile strength, tensile strain, load to failure, tangent modulus, and compliance from the data collected while the specimen was under tension.

Puncture Testing

<u>Standard</u>: ASTM D4833

<u>Method</u>:

1. Clamp the specimen in between the stand and the top part of the puncture apparatus with the hole. The specimen should be clamped in such a way that it extends till at least the end of the plate.
2. Using the puncture tip that was constructed in SolidWorks poke the different specimens to determine the puncture strength.
3. The load range of the Instron should be set so the rupture happens between 10% and 90% of the full-scale load.

4. Test at a speed of 300 ± 10 mm/min or 12 ± 0.5 in/min until the puncture rod ruptures the specimen.
5. Set up Bluehill (see "Bluehill Setup" above)
6. Read the puncture resistance from the greatest force registered on the recording instrument during the test. If there is double peak, report FIRST value even if second is higher.
7. Calculate average and standard deviation of puncture resistance if doing multiple trials for each specimen (n=3).

Peel Testing

Standard: ASTM D903

Method:

1. Hold specimens in the testing machine by grips which clamp firmly and prevent slipping at all times.
2. The rate of separation is 150 mm (6in.)/min at an angle of approximately 180°.
3. Set up Bluehill (see "Bluehill Setup" above).
4. The capacity of the machine is such that the maximum applied tension during test does not exceed 85% nor be less than 15% of the rated capacity.
5. The dimensions of test specimen are 25 by 152.4 mm (1 by 6 in).
6. To maintain a separation rate of 152.4 mm (6 in.)/min the specimen is to be relatively non-extensible in the expected loading range. Where a material is sufficiently extensible to lessen radically the separation rate, back it up with a suitable non-extensible material.
7. Test materials are to be thick enough to withstand the expected tensile pull but not over 3 mm (1⁄8 in.).
8. Determine the actual peel or stripping strength by drawing on the autographic chart the best average load line that will accommodate the recorded curve.

Clean-Up

1. Bag all specimen samples in red biohazard bags.
2. Place in freezer in GH207.
3. Notify Lisa Wall for removal.

Appendix F: ASTM D412 Tensile Testing Raw Data – Biological Tissue

Tensile Testing
Specimen: Bovine

Sample Dimensions – Bovine Colon

	Length (mm)	Width (mm)	Thickness (mm)
Sample 1	137.65	23.25	1.61
Sample 2	137.00	21.50	1.05
Sample 3	148.00	23.27	1.09
Sample 4	100.00	30.88	1.35
Sample 5	117.00	23.13	1.05
Sample 6	108.00	23.57	1.51
Avg ± SD	124.5 ± 19.03	24.27 ± 3.32	1.28 ± 0.25

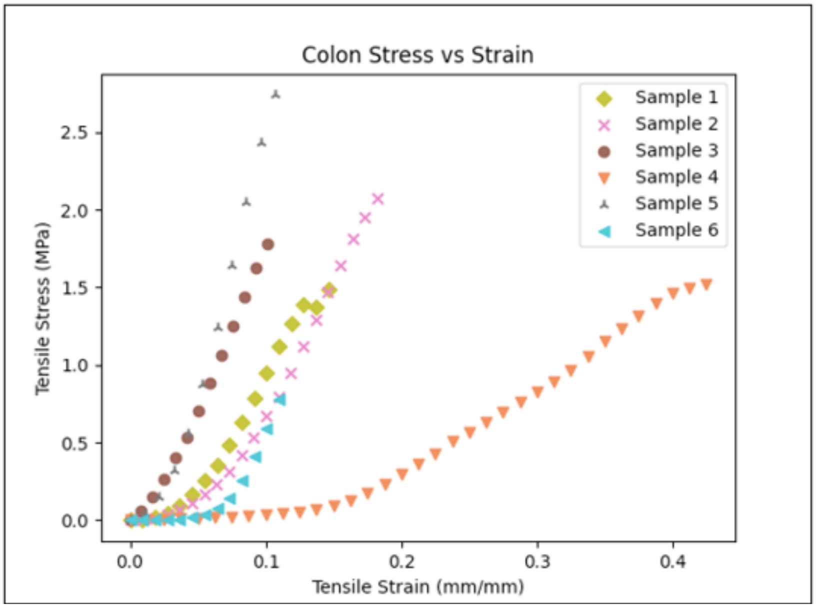
Sample Dimensions- Bovine Small Intestine

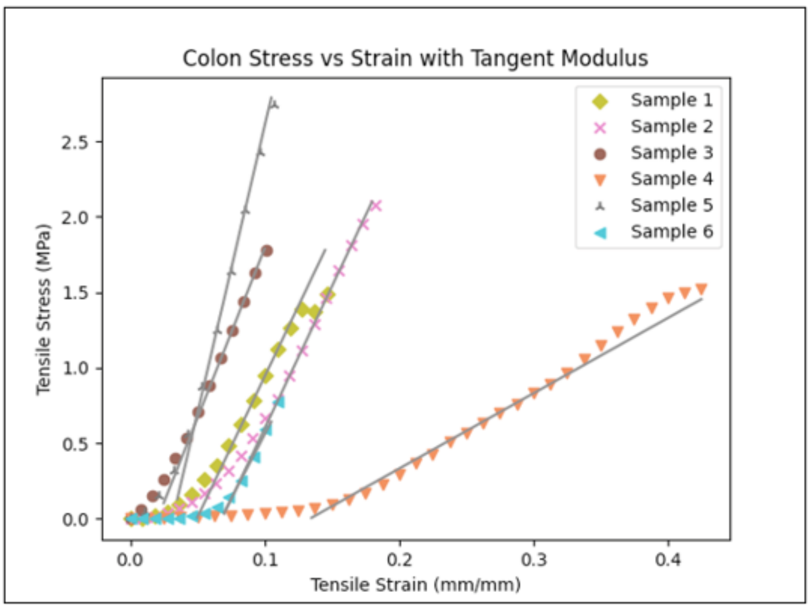
	Length (mm)	Width (mm)	Thickness (mm)
Sample 1	100.29	11.57	1.06
Sample 2	400.44	24.98	1.97
Sample 3	117.86	24.23	1.30
Sample 4	113.12	24.95	1.95
Sample 5	116.30	29.95	2.54
Sample 6	115.48	31.77	1.51
Avg ± SD	160.58 ± 117.68	24.58 ± 7.07	1.72 ± 0.54

Sample Dimensions- Bovine Mesentery

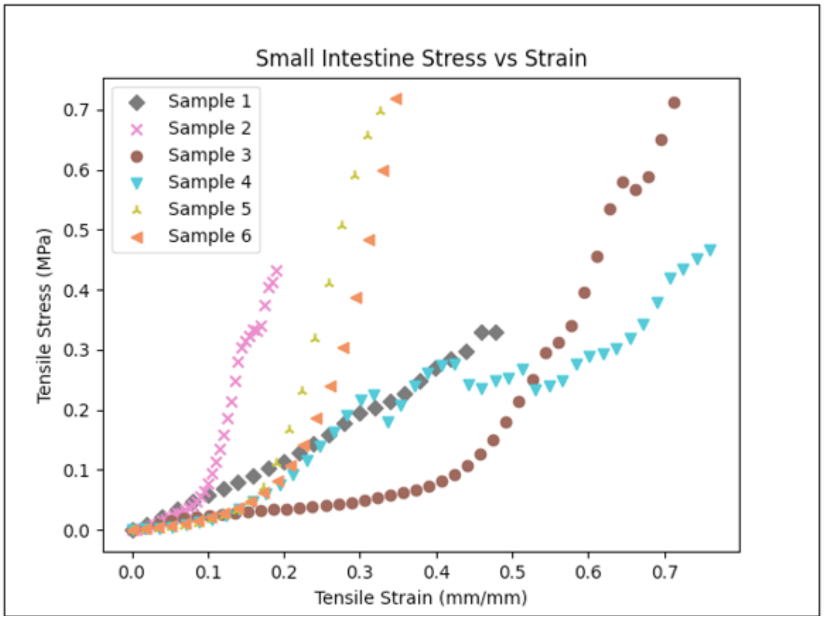
	Length (mm)	Width (mm)	Thickness (mm)
Sample 1	129.00	41.61	1.90
Sample 2	140.00	31.31	3.05
Sample 3	158.00	43.04	2.29
Avg ± SD	142.33 ± 14.64	38.65 ± 6.40	2.41 ± 0.58

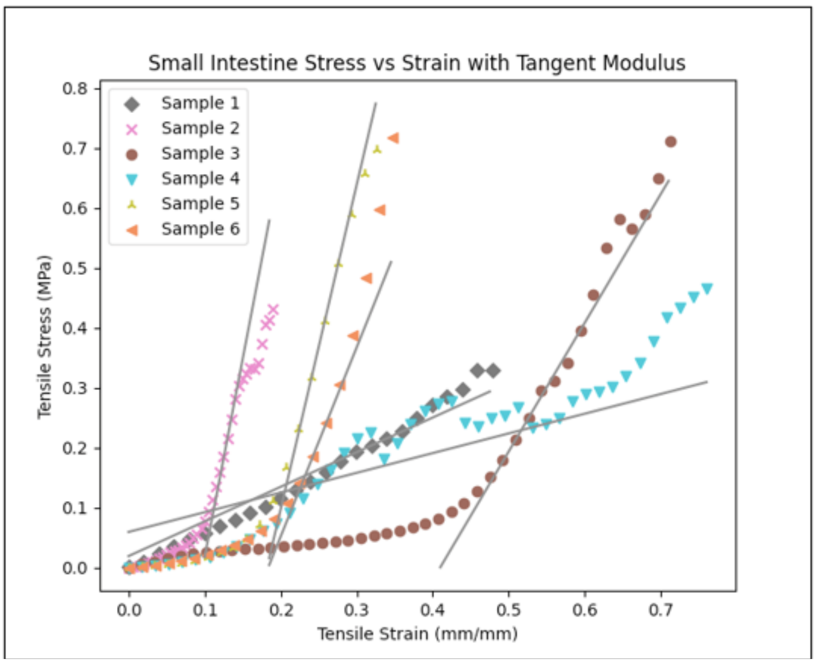
Stress-Strain Graphs- Bovine Colon



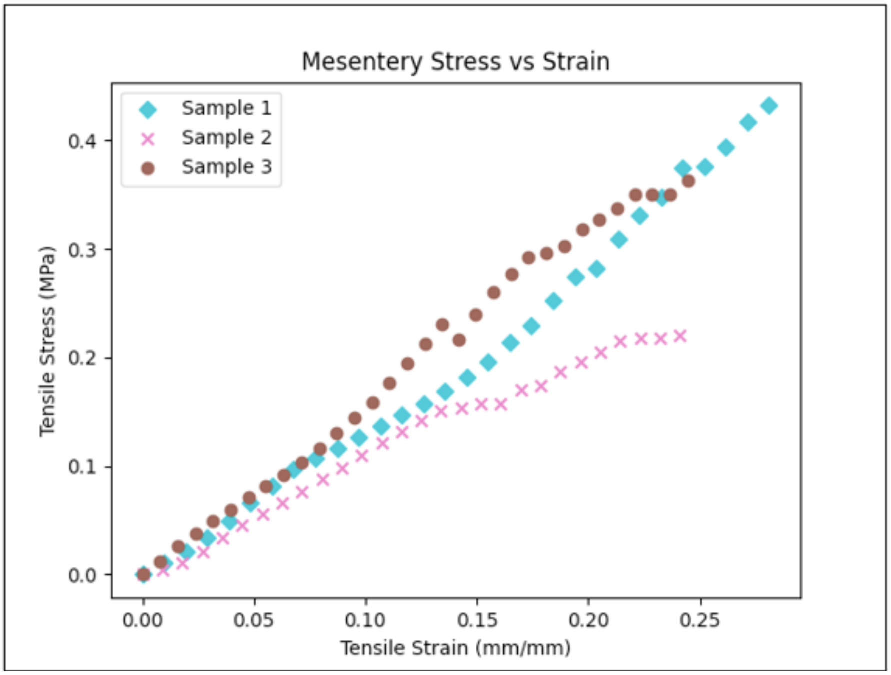


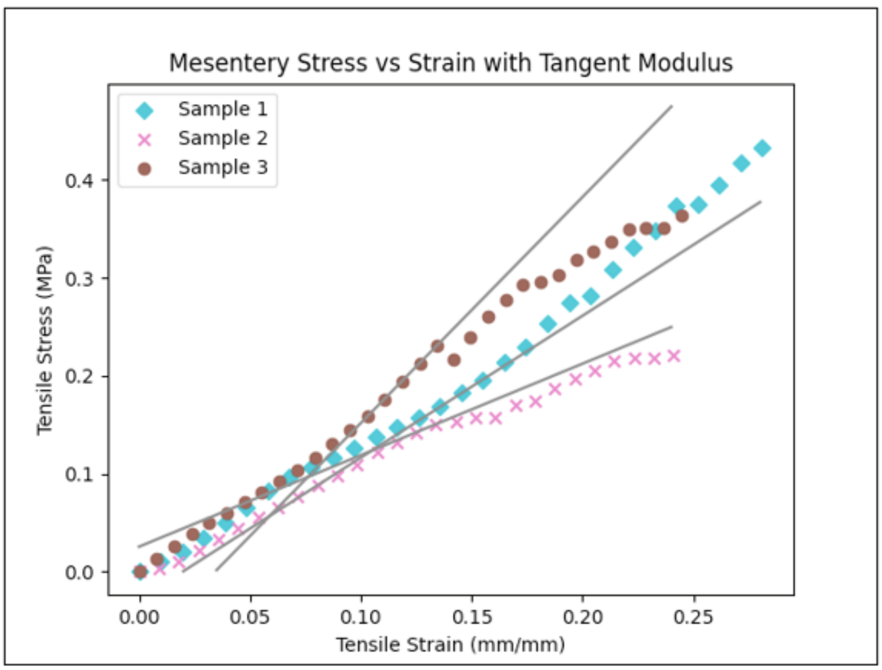
Stress-Strain Graphs- Bovine Small Intestine





Stress-Strain Graphs- Mesentery





Mechanical Data Tables- Bovine Colon

	UTS (MPa)	Strain at Failure	Tangent Modulus	Load to Failure (N)	Compliance (1/MPa)
Sample 1	1.52	0.15	18.63	57.04	0.05
Sample 2	2.15	0.19	18.79	48.52	0.05
Sample 3	1.85	0.11	22.46	46.92	0.04
Sample 4	1.52	0.43	4.99	63.4	0.20
Sample 5	2.95	0.12	37.99	71.73	0.03
Sample 6	0.84	0.12	17.08	31.45	0.06

Sample Size (n)	6
Avg UTS ± SD (MPa)	1.81 ± 0.71
Avg Strain at Failure ± SD	0.18 ± 0.12
Avg Tangent Modulus ± SD (MPa)	19.99 ± 10.65
Avg Load to Failure ± SD (N)	53.18 ± 14.12
Avg Compliance ± SD	0.07 ± 0.06

Mechanical Data Tables- Bovine Small Intestine

	UTS (MPa)	Strain at Failure	Tangent Modulus (MPa)	Load to Failure (N)	Compliance (1/MPa)
Sample 1	0.34	0.49	0.59	4.14	2.04
Sample 2	0.43	0.19	6.61	21.29	5.26
Sample 3	0.74	0.73	2.15	23.43	1.37
Sample 4	0.47	0.76	0.33	22.93	1.32
Sample 5	0.70	0.33	5.42	53.08	3.03
Sample 6	0.80	0.36	3.16	38.46	2.78

Sample Size (n)	6
Avg UTS ± SD (MPa)	0.58 ± 0.19
Avg Strain at Failure ± SD	0.48 ± 0.23
Avg Tangent Modulus ± SD (MPa)	3.04 ± 2.55
Avg Load to Failure ± SD (N)	27.22 ± 16.71
Avg Compliance ± SD	2.63 ± 1.47

Mechanical Data Tables- Bovine Mesentery

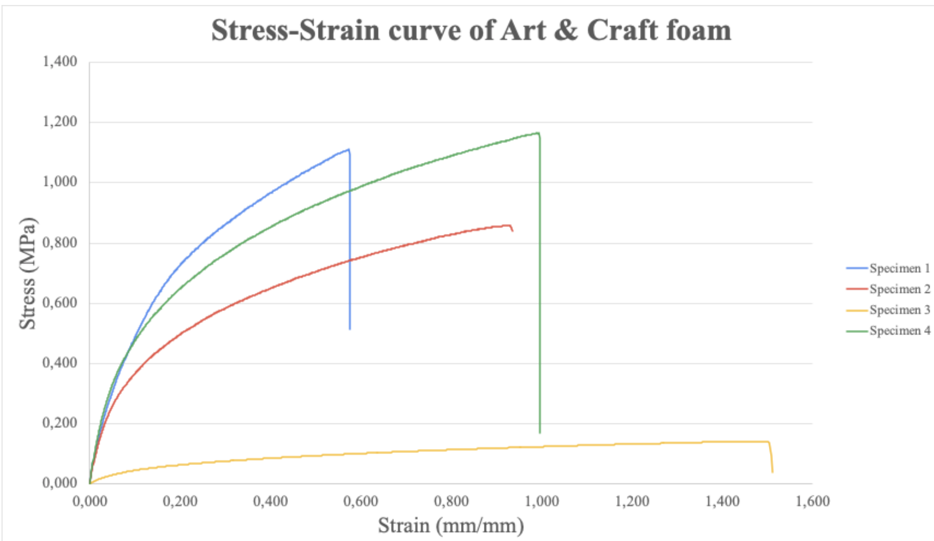
	UTS (MPa)	Strain at Failure	Tangent Modulus (MPa)	Load to Failure (N)	Compliance (1/MPa)
Sample 1	0.43	0.28	1.45	34.17	0.69
Sample 2	0.22	0.22	0.93	21.10	1.08
Sample 3	0.37	0.37	2.31	36.10	2.70

Sample Size (n)	3
Avg UTS ± SD (MPa)	0.34 ± 0.11
Avg Strain at Failure ± SD	0.29 ± 0.08
Avg Tangent Modulus ± SD (MPa)	1.56 ± 0.70
Avg Load to Failure ± SD (N)	30.46 ± 8.16
Avg Compliance ± SD	1.49 ± 1.07

Appendix G: ASTM D412 Tensile Testing Raw Data – Synthetic Material

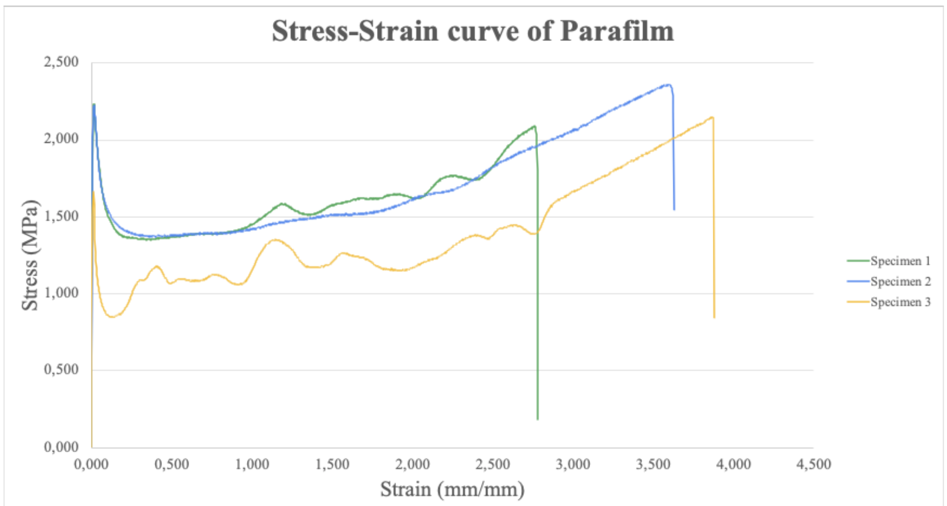
Graph 1: Art & Crafts Foam

Sample Dimensions			
Sample	Length (mm)	Thickness (mm)	Width (mm)
1	203.2	1	10
2	203.2	0.7112	25.4
3	100	1	10
4	203.3	0.6604	25.4



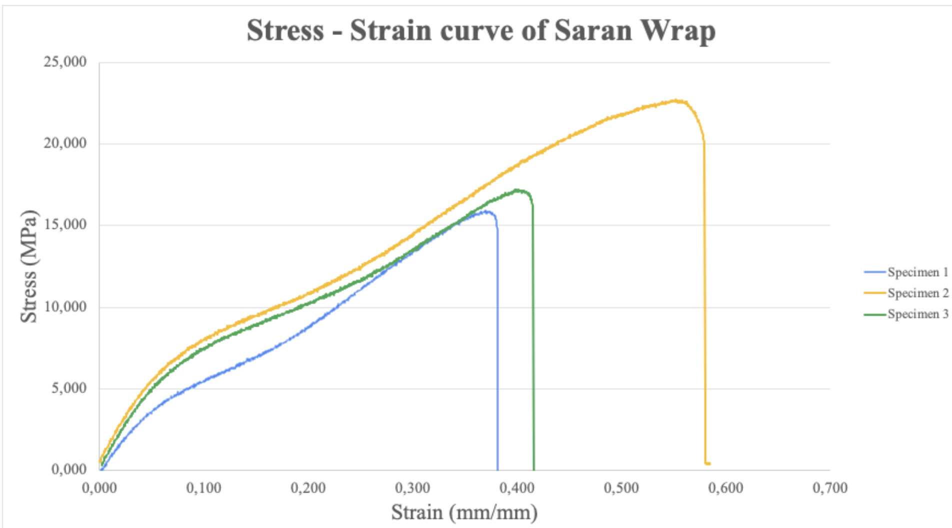
Graph 2: Parafilm

Sample Dimensions			
Sample	Length (mm)	Thickness (mm)	Width (mm)
1	152.4	0.127	25.4
2	152.4	0.127	25.4
3	152.4	0.1524	25.4



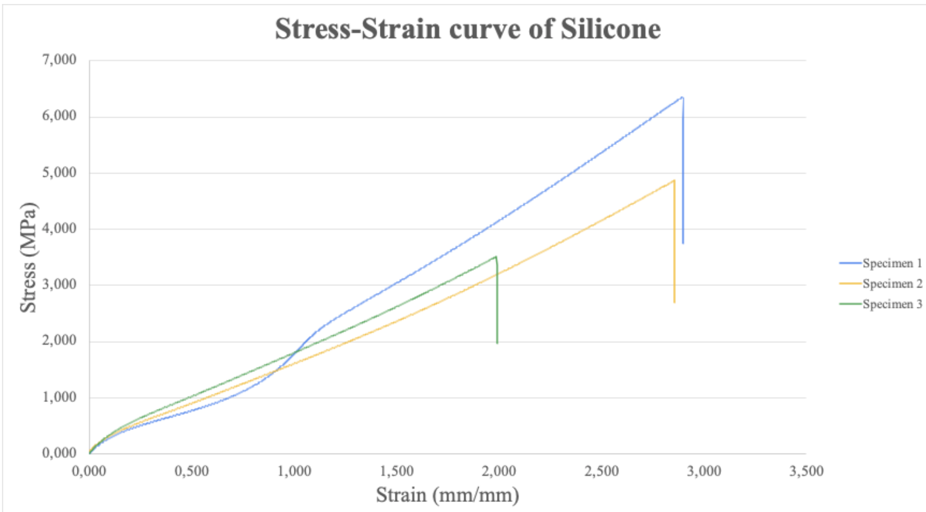
Graph 3: GLAD® Cling Wrap

Sample Dimensions			
Sample	Length (mm)	Thickness (mm)	Width (mm)
1	254	0.0127	12.827
2	254	0.0127	12.827
3	254	0.0127	12.827



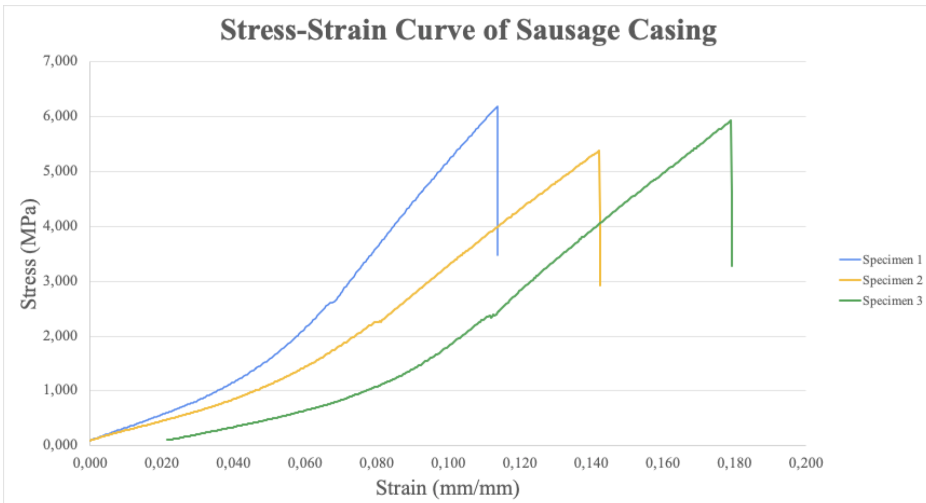
Graph 4: Stove Silicone

Sample Dimensions			
Sample	Length (mm)	Thickness (mm)	Width (mm)
1	152.4	1.6256	14.2748
2	152.4	1.6256	14.2748
3	152.4	1.6256	14.2748



Graph 5: Sausage Casing

Sample Dimensions			
Sample	Length (mm)	Thickness (mm)	Width (mm)
1	228.6	0.3048	15.8496
2	228.6	0.3048	15.8496
3	228.6	0.3048	15.8496



Appendix H: Synthetic Material Product Information

Potential Glue Materials

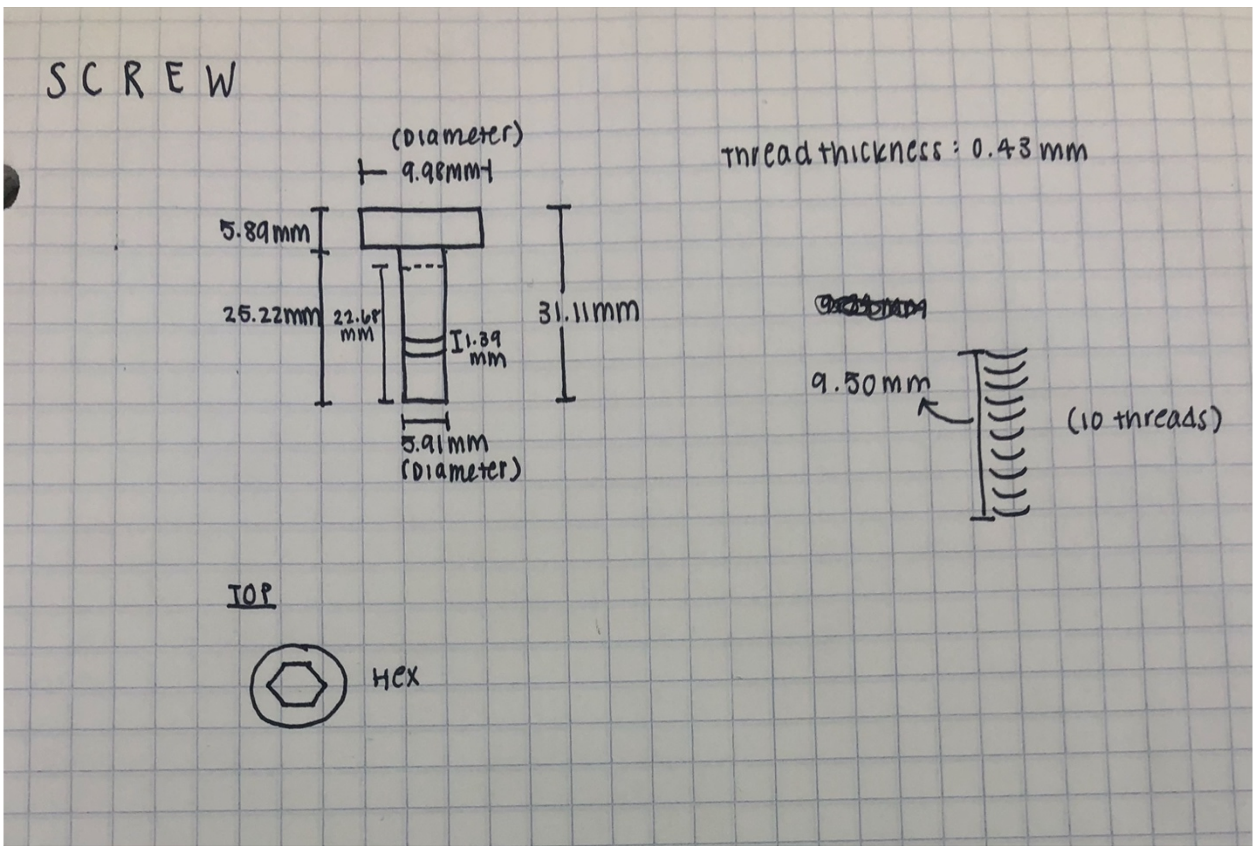
Product	Manufacturer	Catalog Number
Permanent Double Sided Tape	Scotch®	6137H-2PC-MP
Removable Adhesive Nano Gel Tape	Honwally	HW-020T
Rubber Cement	Elmer's®	E904
Loctite® Spray Adhesive	Loctite®	2235316
Gum	Mehron®	118
Knox Original Unflavored Gelatin	Knox®	43000048689
Soothing Gel Pads for Breastfeeding	Medela®	87123NA
Hydrogel Eyepatch	GreenLife®	B07PK59HL9
SoloSite Wound Gel	Smith & Nephew®	449600

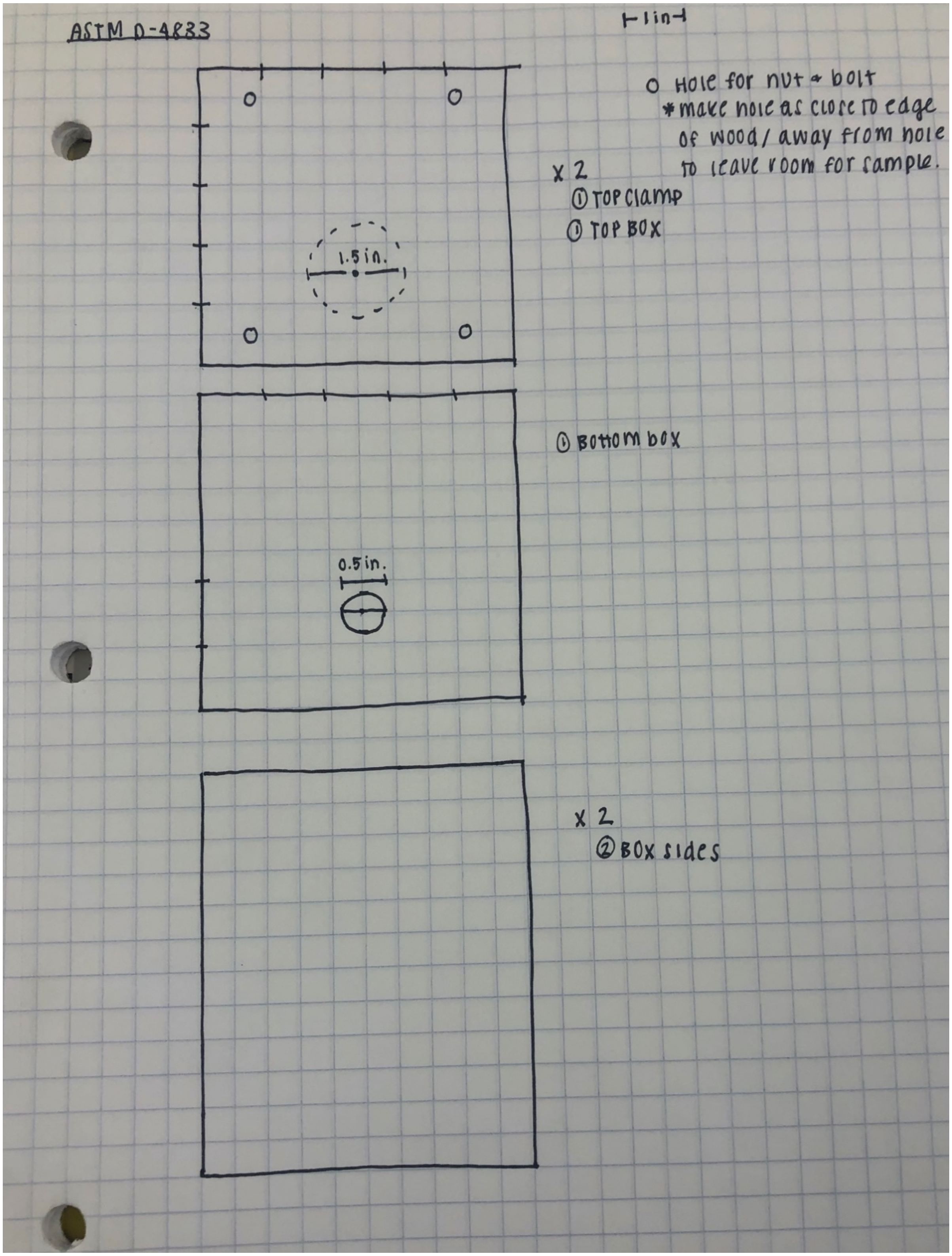
Potential Organ Materials

Product	Manufacturer	Catalog Number
High Density Cushion Craft Foam	Linenspa®	LS2247225UF
OOMOO 25 Silicone	Smooth-On®	SMOoomoo25
Press'n Seal Plastic Food Wrap	GLAD®	0010
Sylgard 182 Silicone Elastomer Kit (PDMS)	Dow Corning®	Sylgard 182
Silicone Kitchen Stove Counter Gap Cover Long & Wide Gap Filler	CozyKit®	B07N4S9J97
Edible Collagen Casings Dry Pig Sausage Casing Tube	ECYC®	12828
All Purpose Laboratory Film, Semi-Transparent	Parafilm M®	PM992
EVA Foam Sheets	Better Office Products®	B089DPDYKV

Appendix I: Schematic and Description of Puncture Fixture

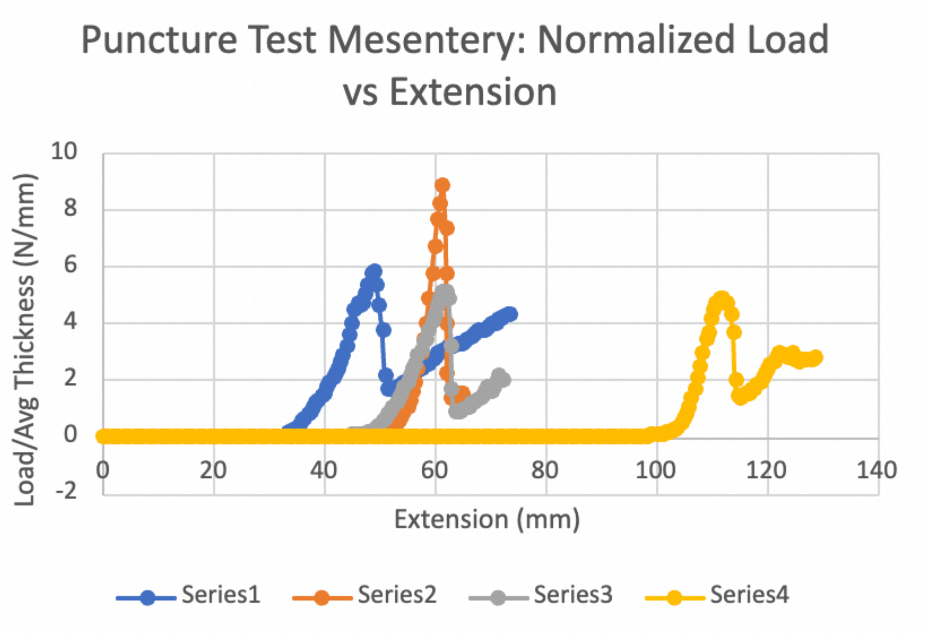
Shown below are the schematics for each part of the puncture fixture with dimensions. The final product of the puncture fixture was fabricated from wood, screws, and a hinge, as shown in Figure 23 in 5.1.2 section of the report. The 1.5 inch hole indicated on the schematic is where the sample would be exposed to the puncture apparatus, which is also shown in that same figure. There are two top wooden plates indicated in the schematic below, which are the parts that will sandwich the sample and expose it to the puncture apparatus to measure puncture force. The sample is secured between the two plates using a clamp to avoid slipping. The bottom of the puncture fixture is secured to the bottom of the Instron using the hex screw that secures all the bottom fixtures to the Instron. This will avoid movement The center of the box is hollow to allow room for the puncture apparatus to puncture through the sample without coming in contact with any other part of the apparatus or coming in contact with the bottom of the Instron machine. By removing the clamping, samples can be removed and inserted between test runs.



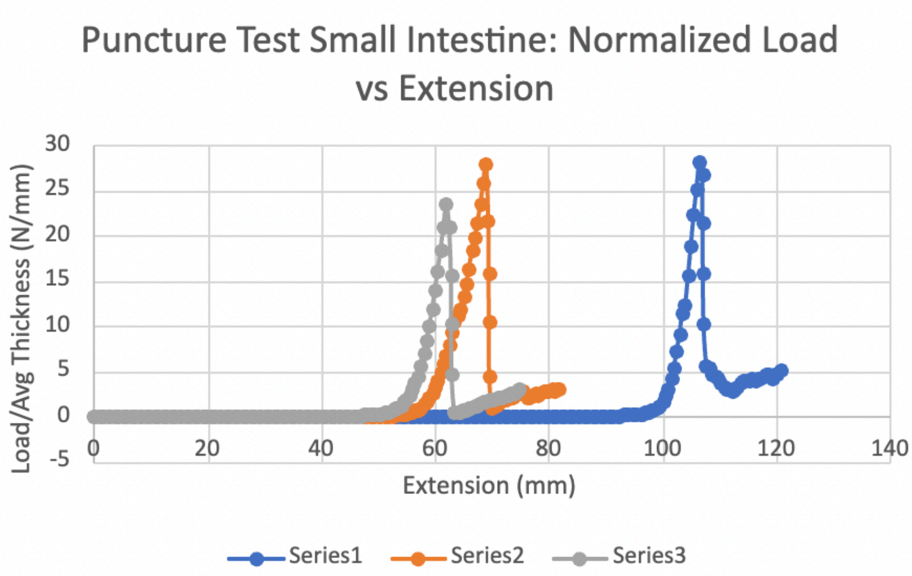

ASTM D-4833
1 in
o Hole for nut + bolt
* make hole as close to edge
of wood / away from hole
to leave room for sample.
x 2
① Top clamp
① Top box
1.5 in.
① bottom box
0.5 in.
x 2
② Box sides

Appendix J: ASTM D4833 Puncture Testing Raw Data

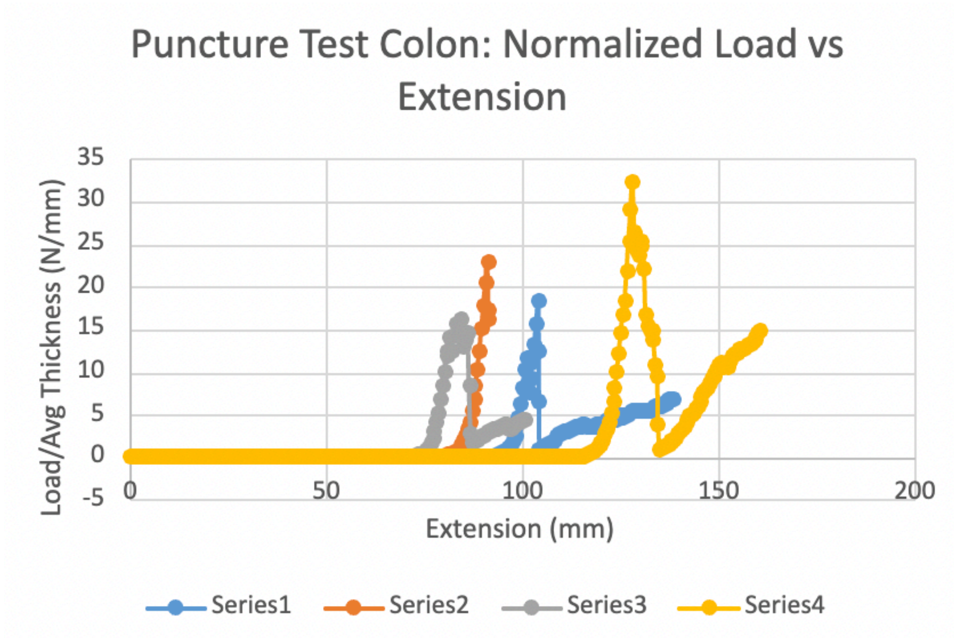
Graph 1: Bovine Mesentery Puncture Force



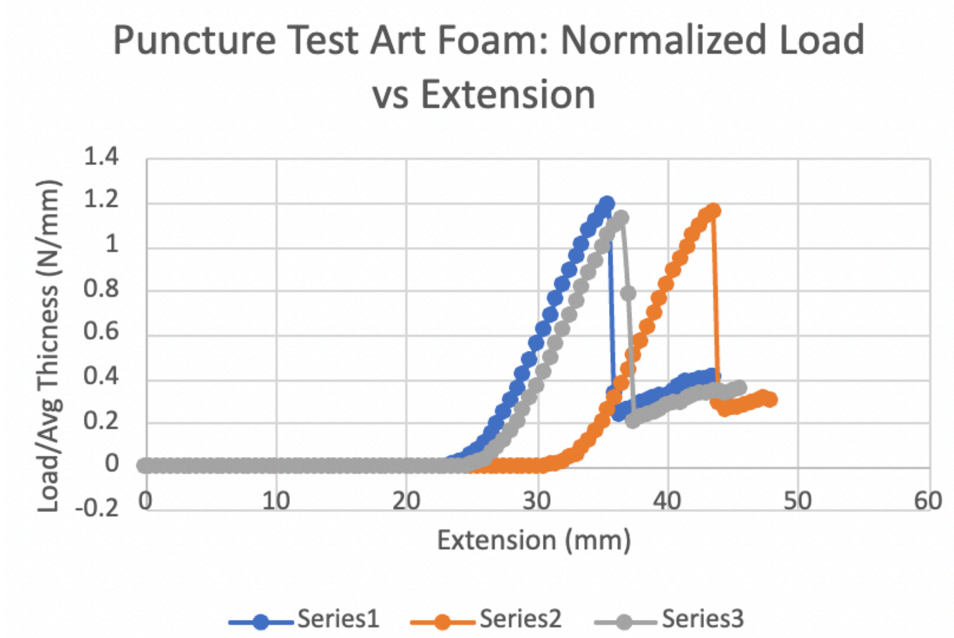
Graph 2: Bovine Small Intestine Puncture Force



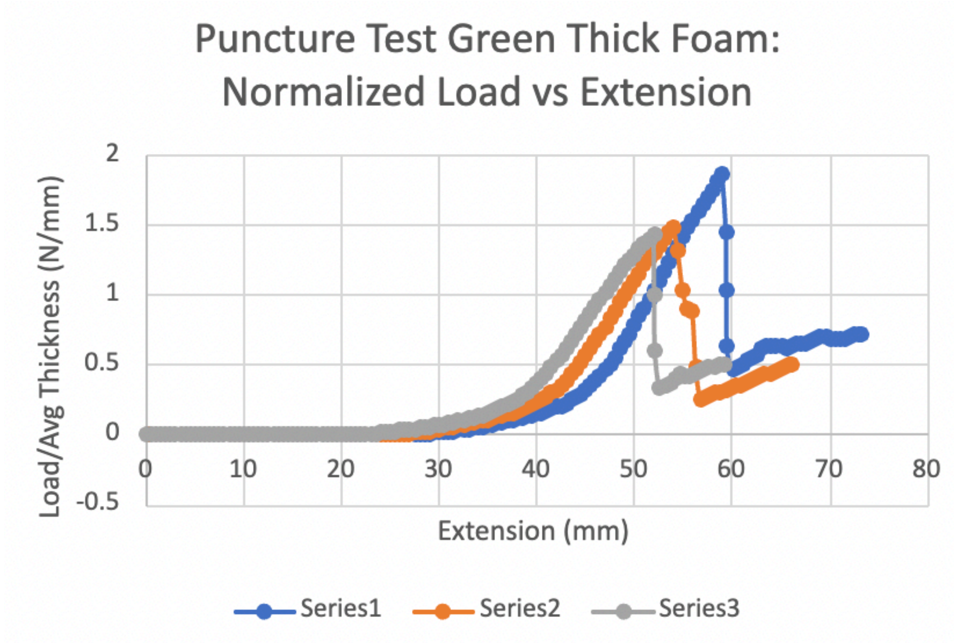
Graph 3: Bovine Colon Puncture Force



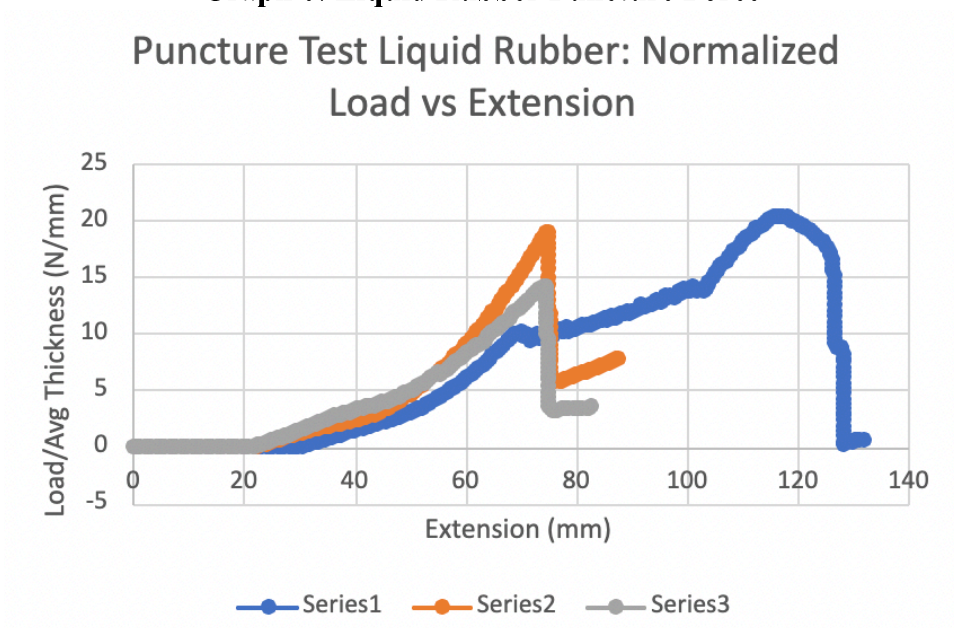
Graph 4: Ethylene vinyl acetate (EVA) Foam Puncture Force



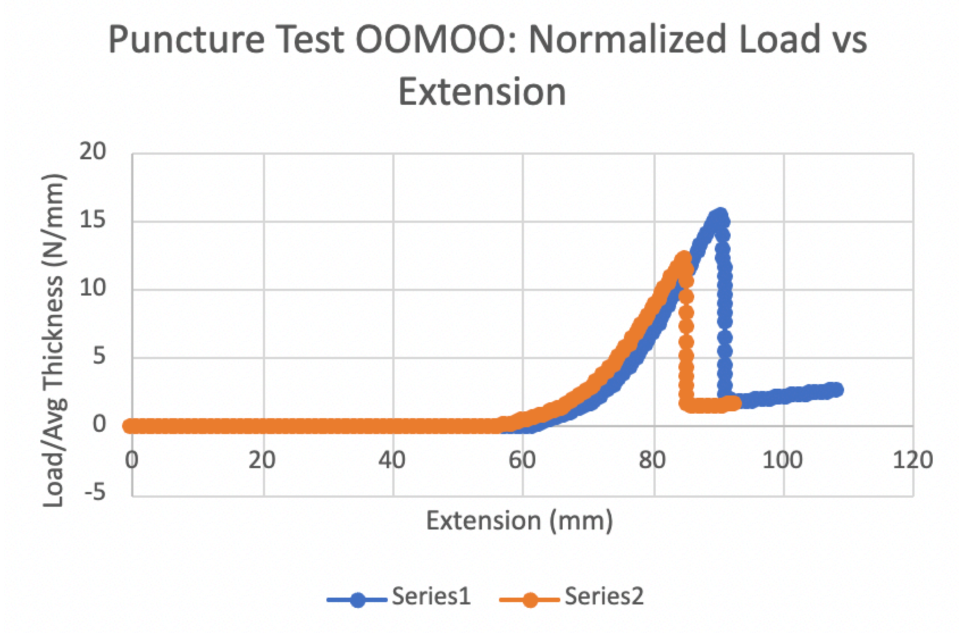
Graph 5: Green Thick Foam Puncture Force



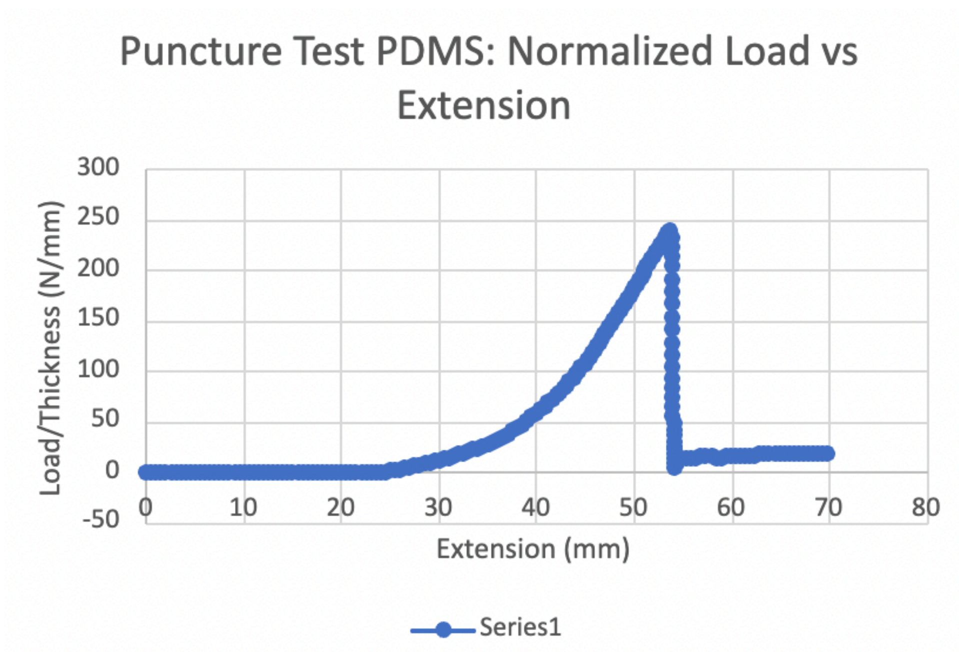
Graph 6: Liquid Rubber Puncture Force



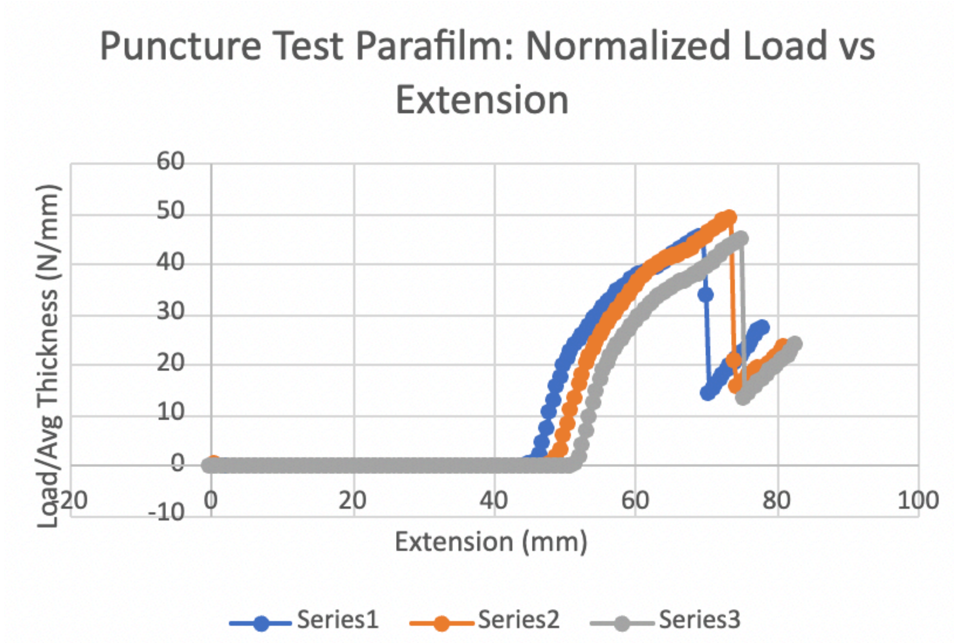
Graph 7: OOMOO™ Puncture Force



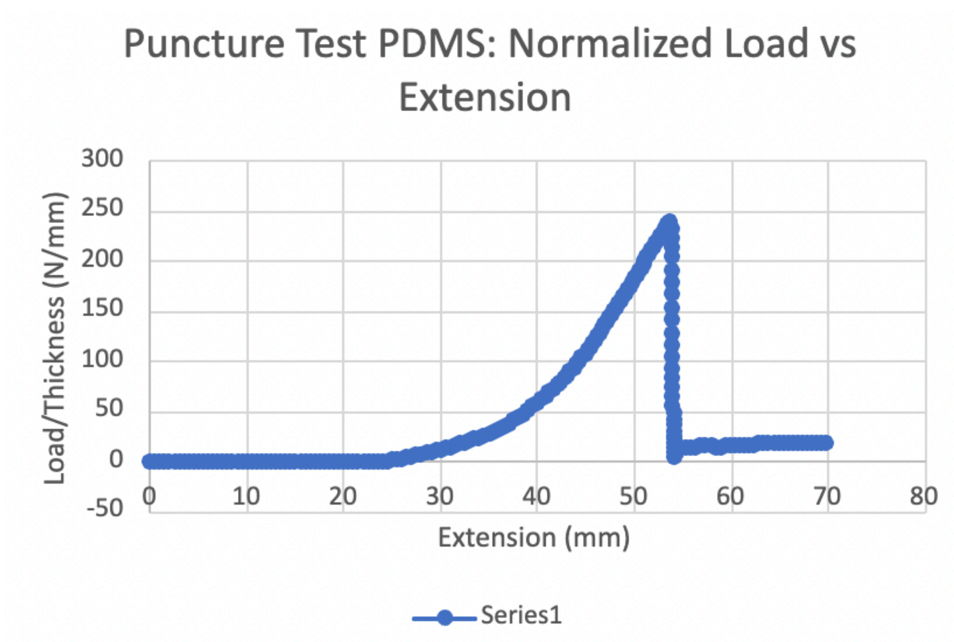
Graph 8: Parafilm Puncture Force



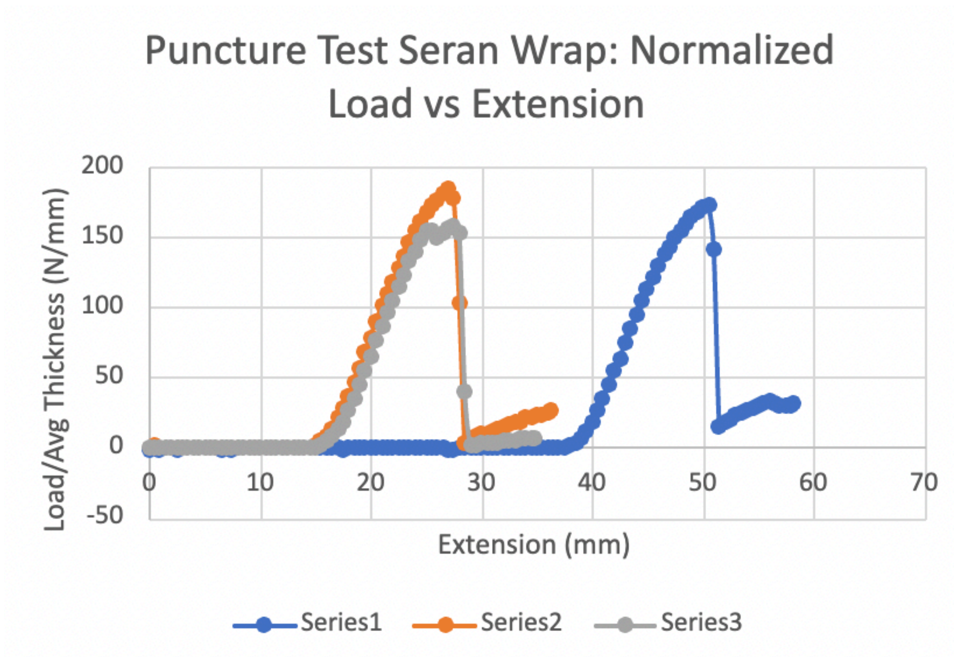
Graph 9: Parafilm Puncture Force



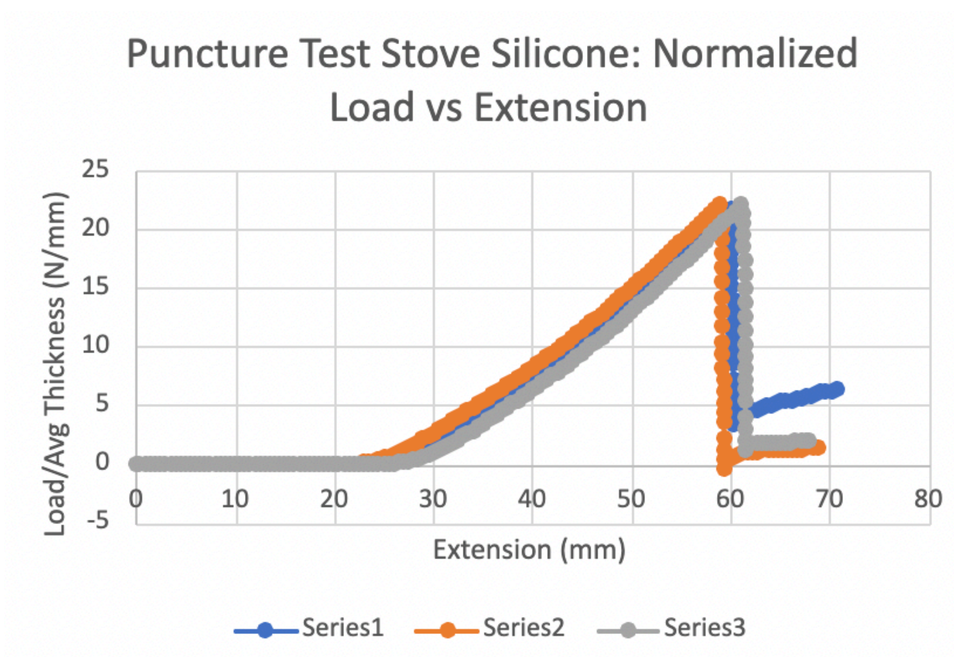
Graph 10: PDMS (Sylgard) Puncture Force



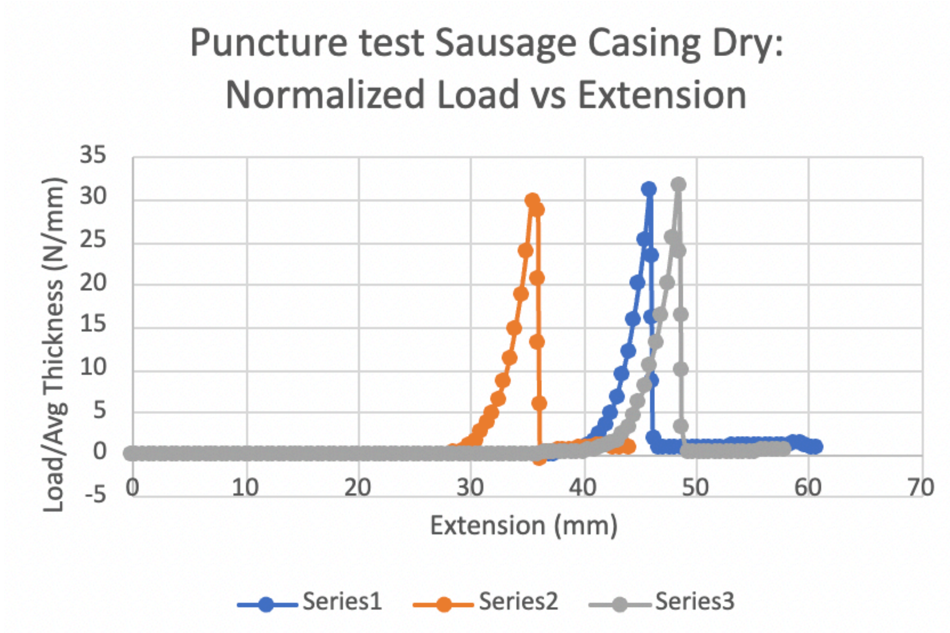
Graph 11: GLAD® Cling Wrap Puncture Force



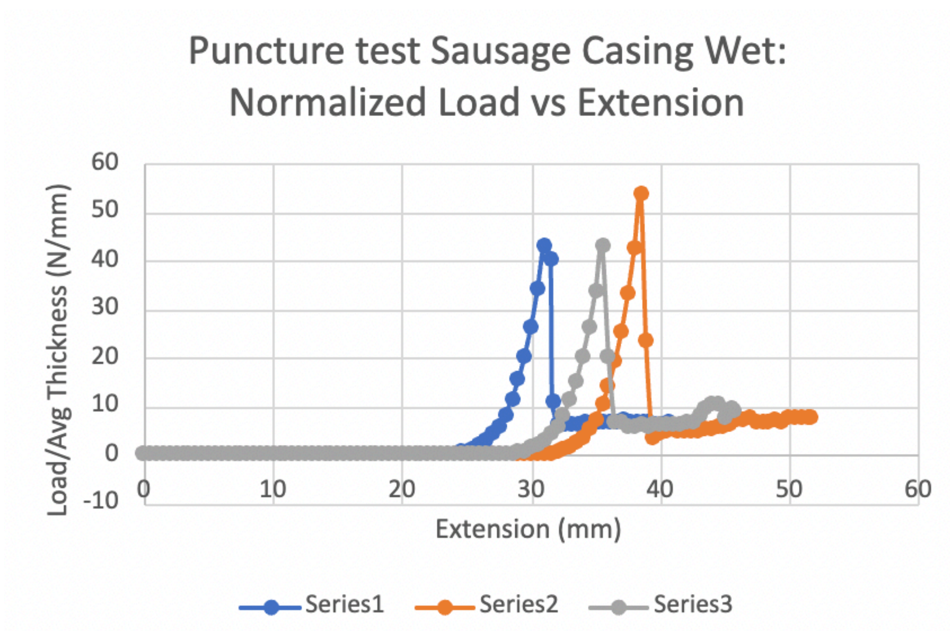
Graph 12: Stove Silicone Puncture Force



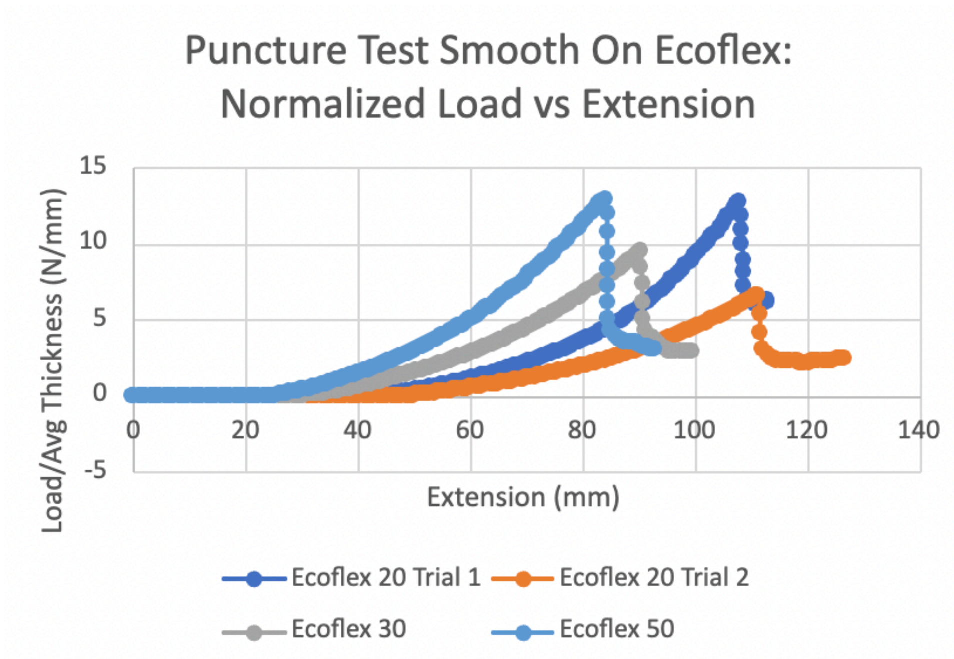
Graph 13: Sausage Casing Dry Puncture Force



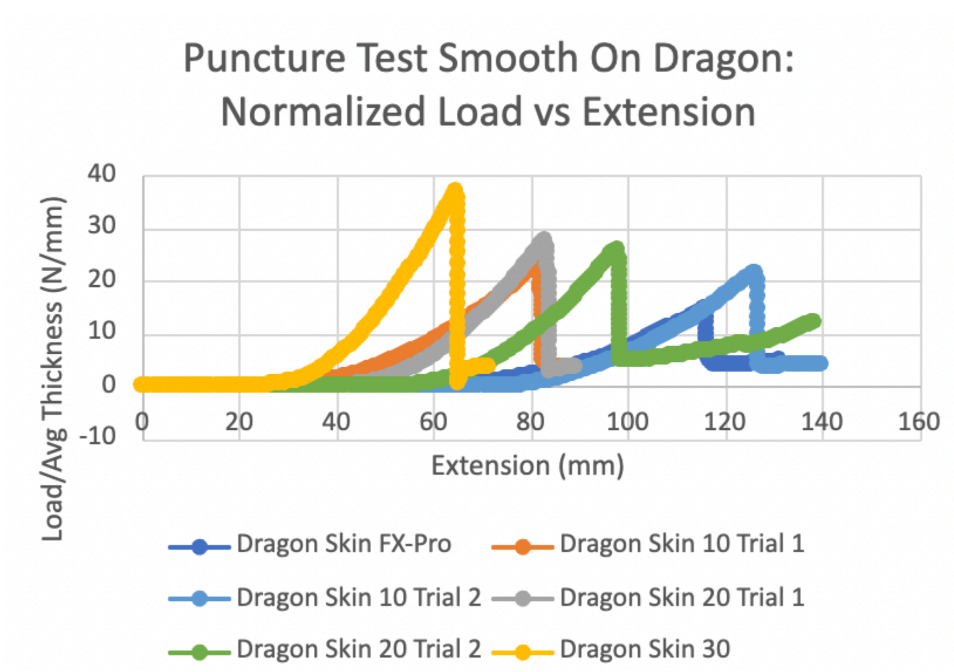
Graph 14: Sausage Casing Wet Puncture Force



Graph 15: Smooth On Ecoflex™ Puncture Force

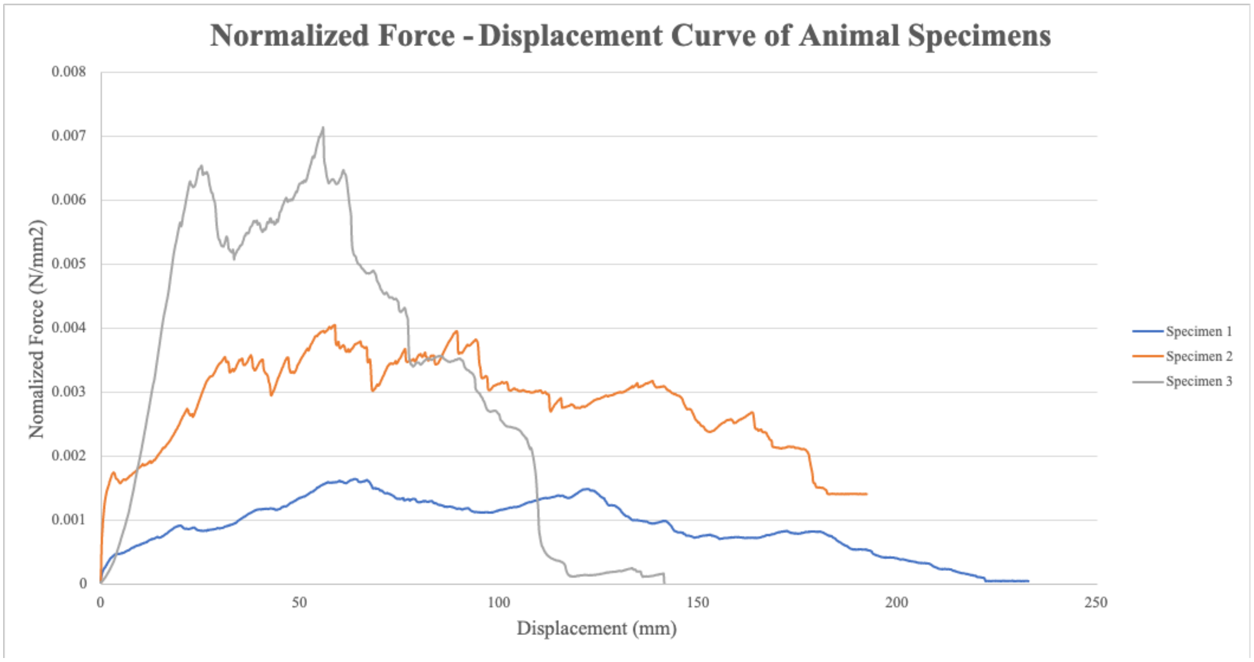


Graph 16: Smooth On Dragon Skin™ Puncture Force

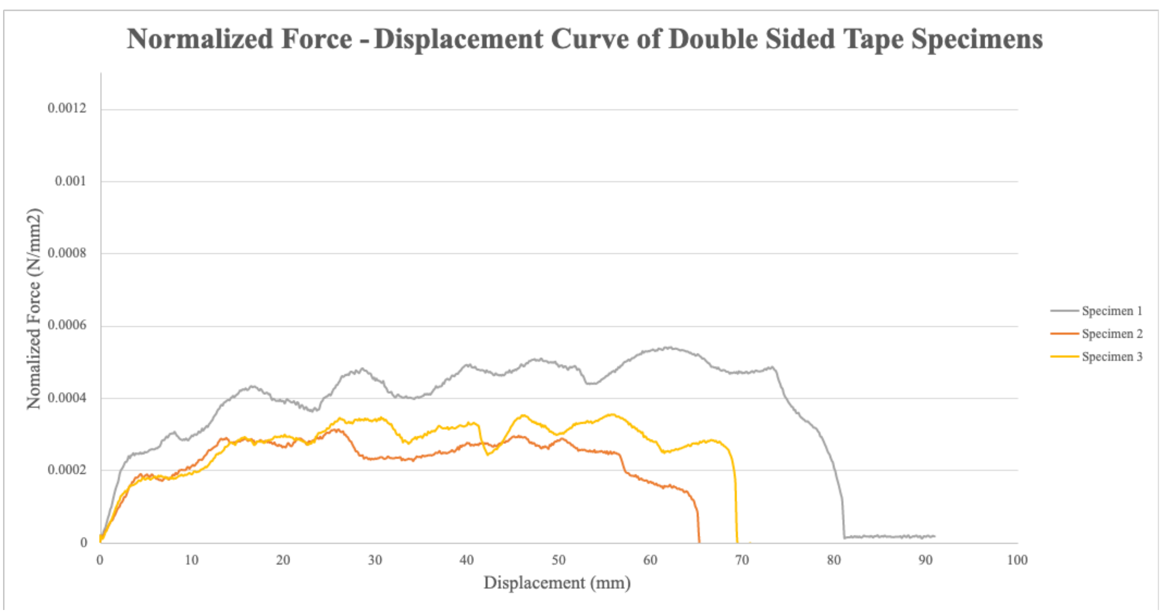


Appendix K: ASTM D903 Peel Testing Raw Data

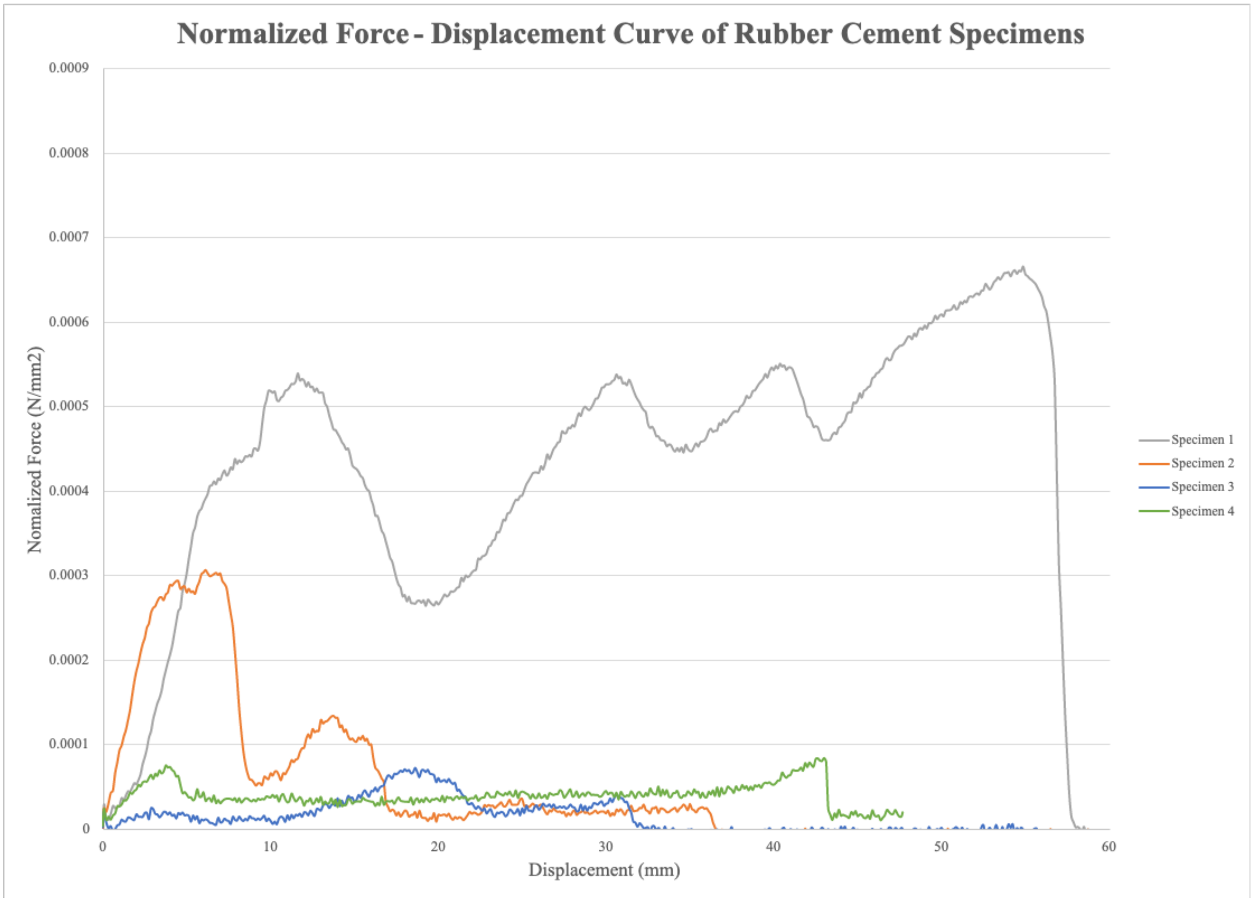
Graph 1: Bovine sample



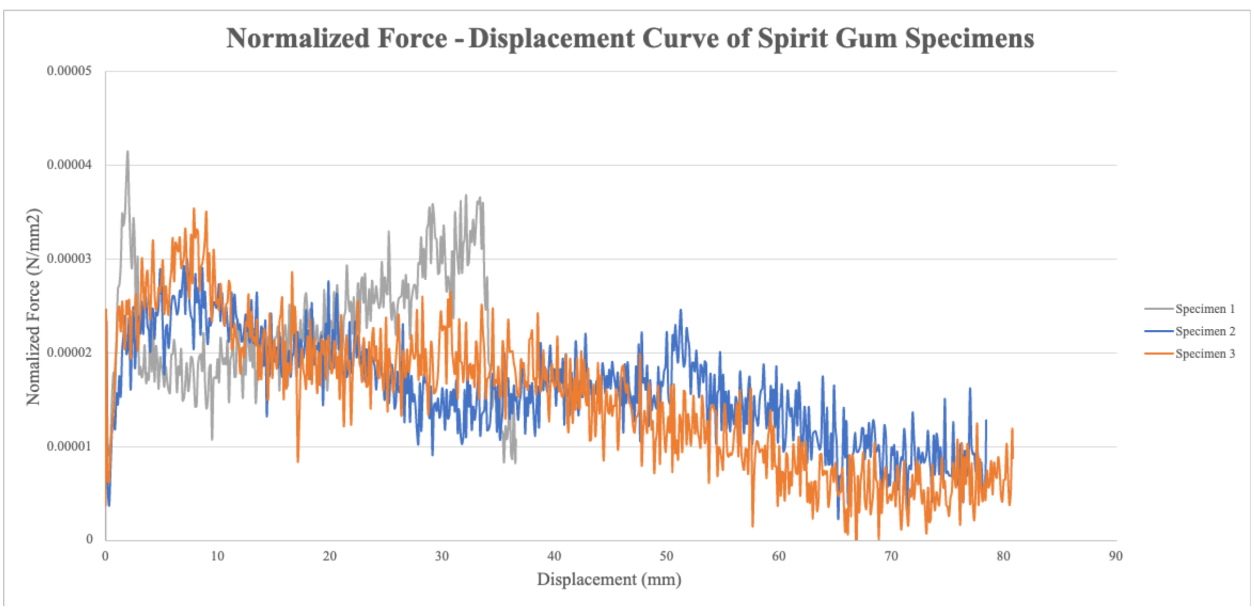
Graph 2: Double Sided Tape



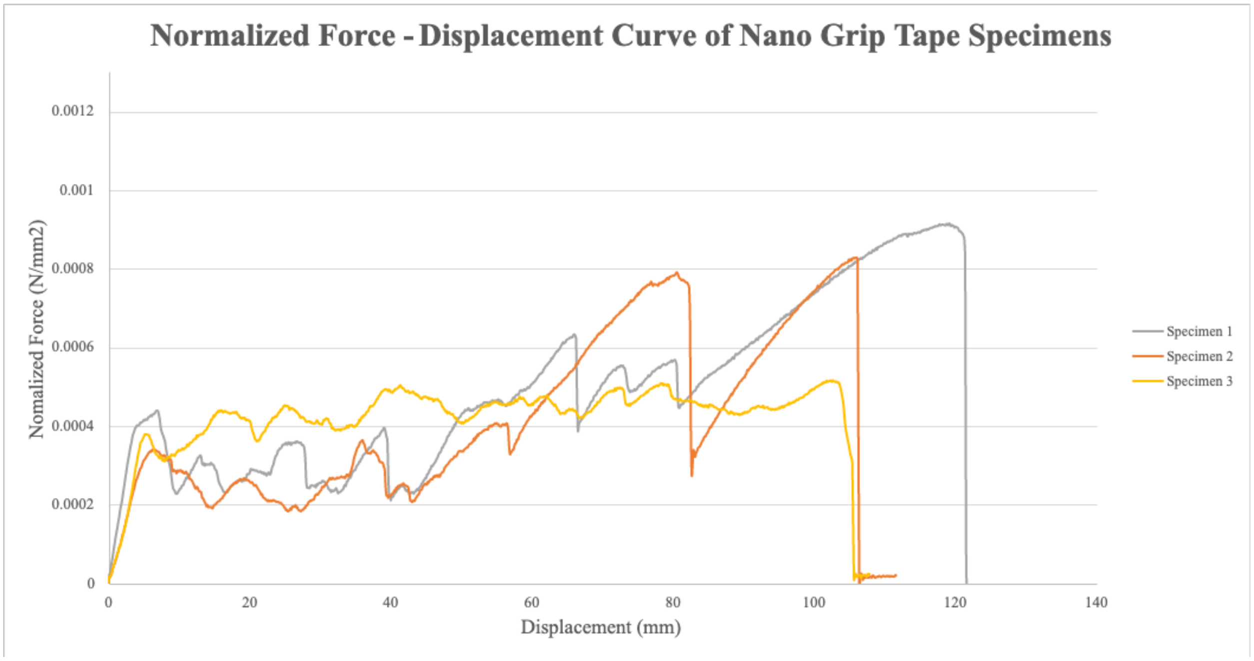
Graph 3: Elmer's® Rubber Cement



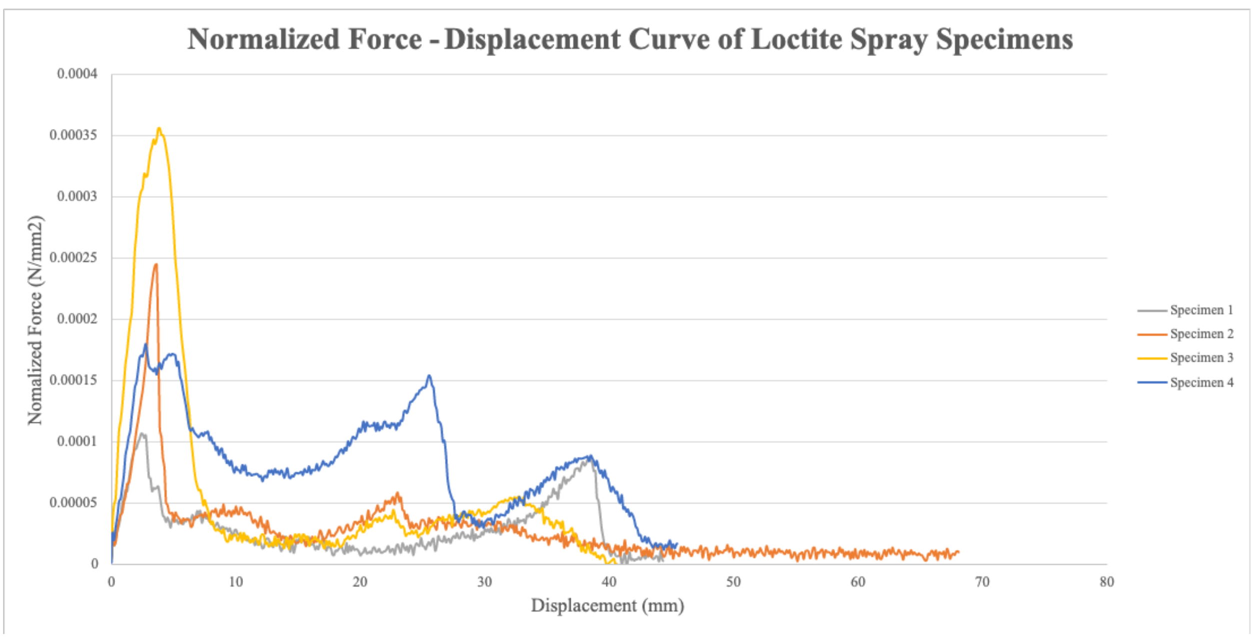
Graph 4: Spirit Gum



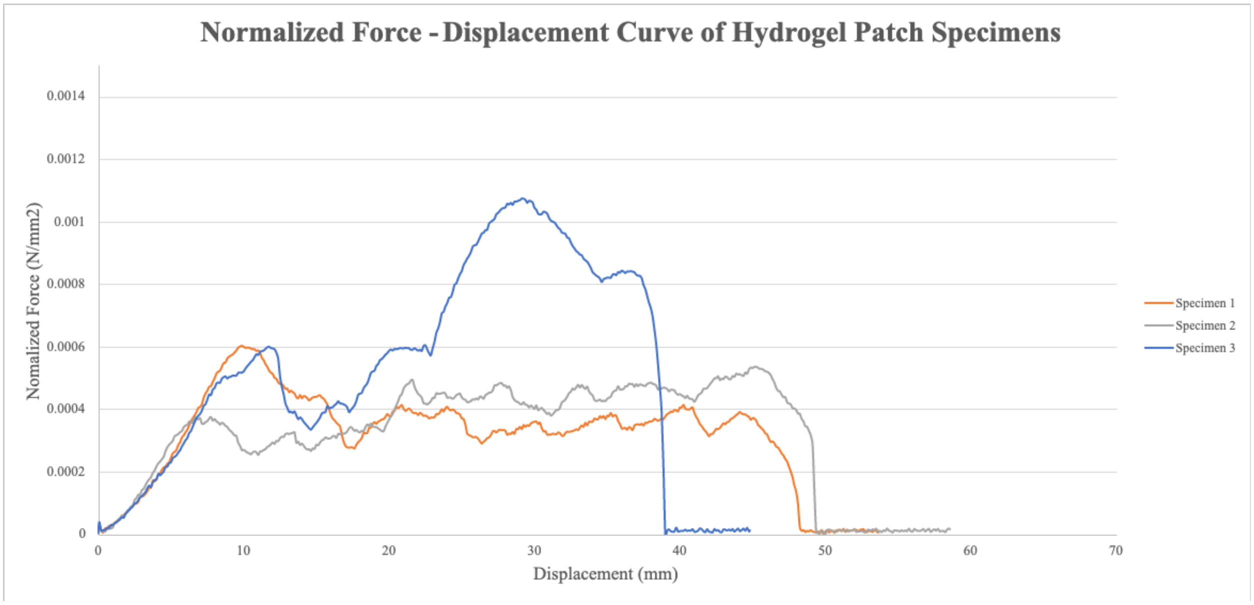
Graph 5: Nano Grip Tape



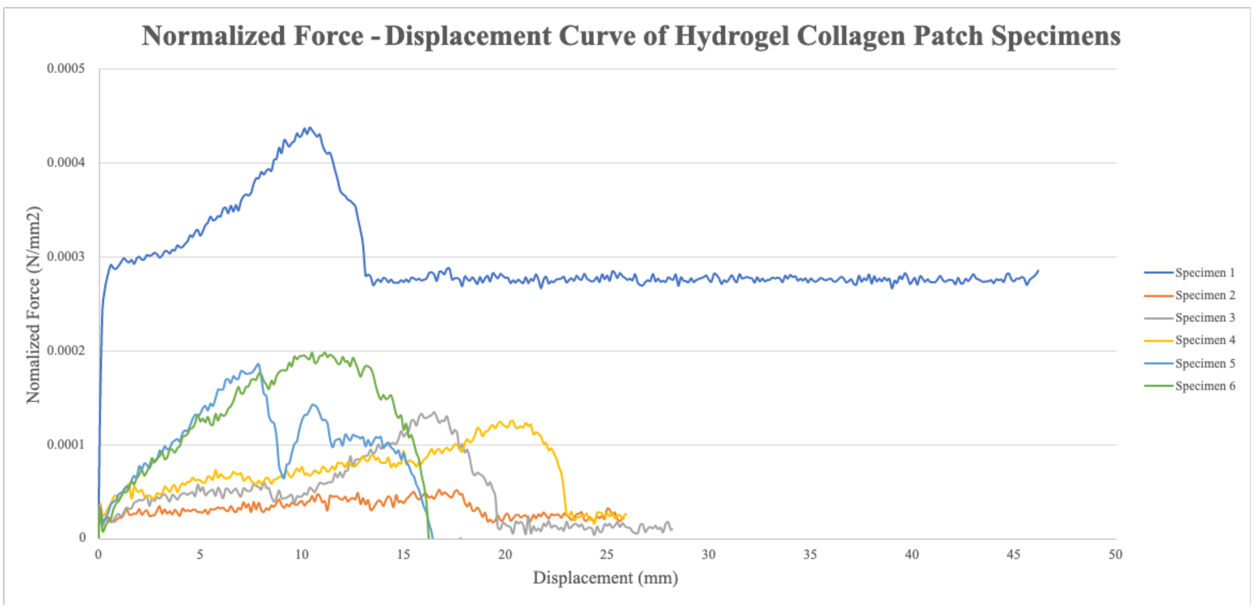
Graph 6: Loctite® Spray Adhesive



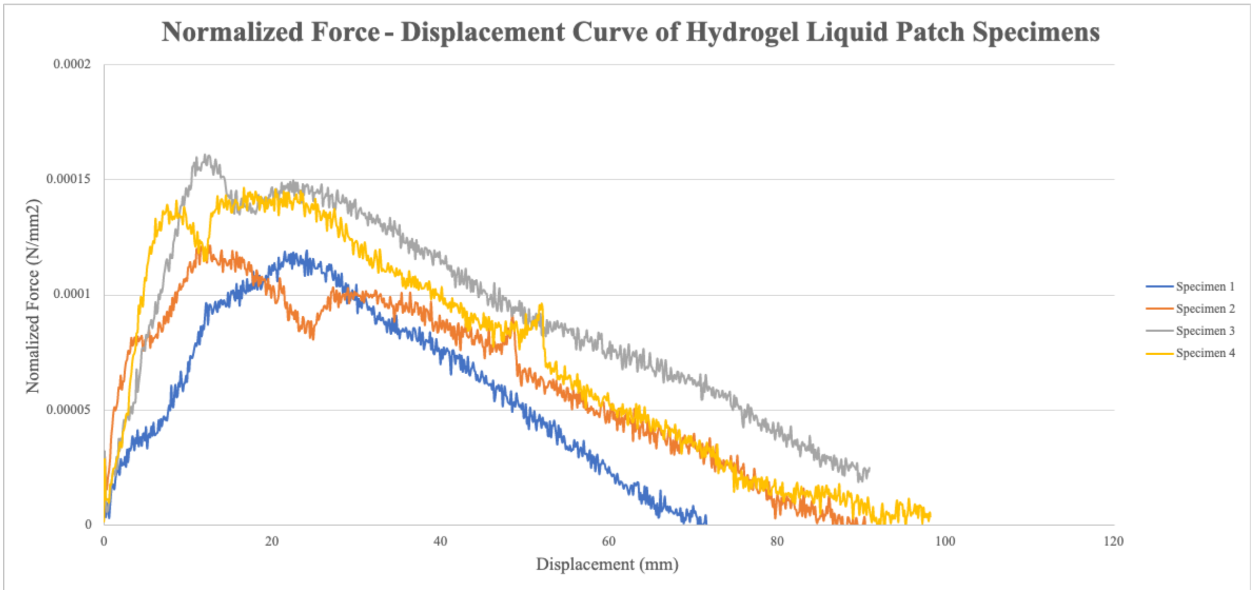
Graph 7: Hydrogel Patch



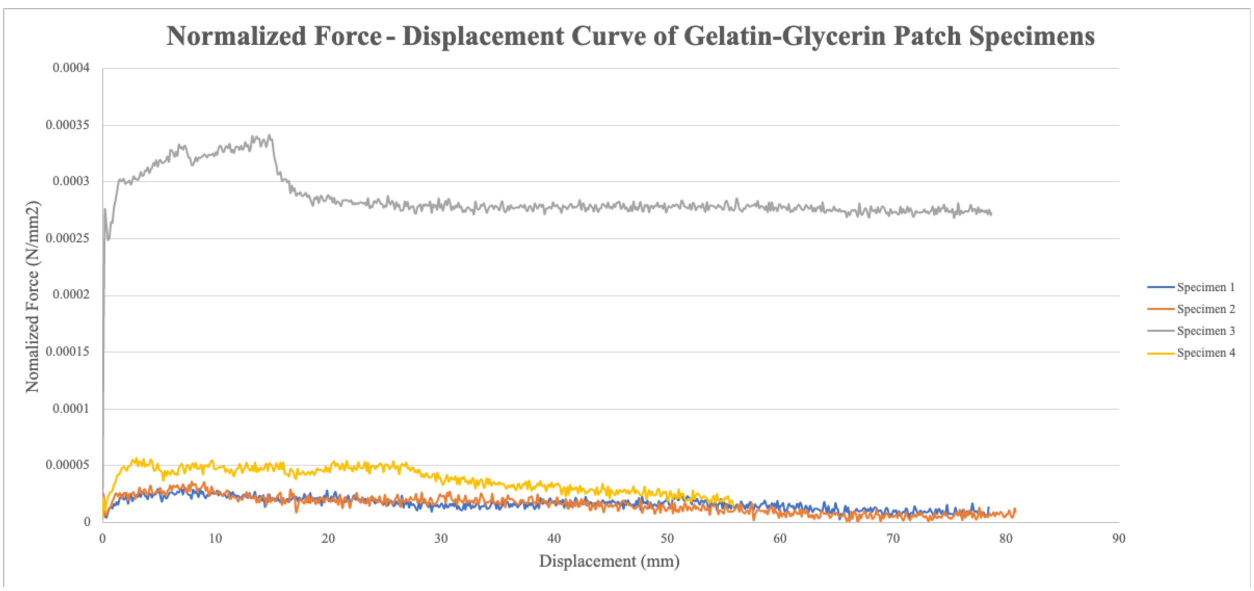
Graph 8: Hydrogel Collagen Patch



Graph 9: Hydrogel Liquid



Graph 10: Gelatin-Glycerin



Appendix L: Bio-realistic Surgical Phantom Survey

Survey Questions

Bio-realistic Surgical Phantom Survey

Please fill out the survey as detailed as possible. Thank you so much for helping our team out. We really appreciate it!

* Required

1. Contact Info (*In case we have further questions) *

2. Name *

3. Year (if Resident)

4. Specialty / Rotation

5. Is it okay to use your responses in our report? (All responses will be anonymous) *

   Mark only one oval.

   - Yes
   - No
   - Other: ____________

Double Sided Tape

6. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

7. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

8. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ______________________

Nano Grip Tape

9. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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10. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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11. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] _______________

Rubber Cement

12. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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13. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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14. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] _______________________

Locite Spray Glue

15. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

16. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

17. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No
- Other: [ ] ____________

Gelatin/Glycerin

18. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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19. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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20. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ______________________

Seran Wrap

21. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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22. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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23. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No
- Other: [ ] ________________________

Stove Silicone Cover

24. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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25. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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26. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ______________________

Sausage Casing

27. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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28. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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29. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] _______________________

Arts and Crafts Foam

30. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

31. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

32. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No
- Other: [ ] ______

Parafilm

33. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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34. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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35. Should we use this material for our model?

Check all that apply.

☐ Yes
☐ No
Other: ☐ ______________________

Oomoo Silicone

36. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

37. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

38. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ______

Smooth On Silicone Samples

39. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

40. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

41. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ____________

Lab Gloves

42. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

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43. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

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44. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ________________________

PDMS

45. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

46. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

47. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ____________________

Green Styrofoam

48. Does this material resemble any specific organ or tissue of the abdominal area? What properties of the material are bio-realistic, if any?

49. On a scale of 1 to 5, how bio-realistic is this material for mimicking parts of the human abdomen? Explain. (1= least bio-realistic, 5= most bio-realistic)

50. Should we use this material for our model?

Check all that apply.

- [ ] Yes
- [ ] No

Other: [ ] ____________________

Final Questions

51. Do you have any material recommendations that we did not bring today?

52. Please describe any other observations/thoughts on the materials

53. Additional Comments

Survey Responses

Year of Residency

6 responses

- Not Resident (Doctor)
- Attending
- 5th year
- 1st year
- medical student
- 5

Area/Specialization

6 responses

- Colorectal
- Colorectal Surgery
- cardiac (general surgery resident)
- general resident
- not sure
- surgical oncology

What forms of laparoscopic training have you received?

6 responses

-
box trainer, cadaver, simulator, intraoperative
in the OR, sim center -- box trainers
sim center - , some stuff at transplant peritoneal catheters, mostly driving camera
one sim session a year ago
OR cases, Simlab laparoscopic FLS course and robotic stuff

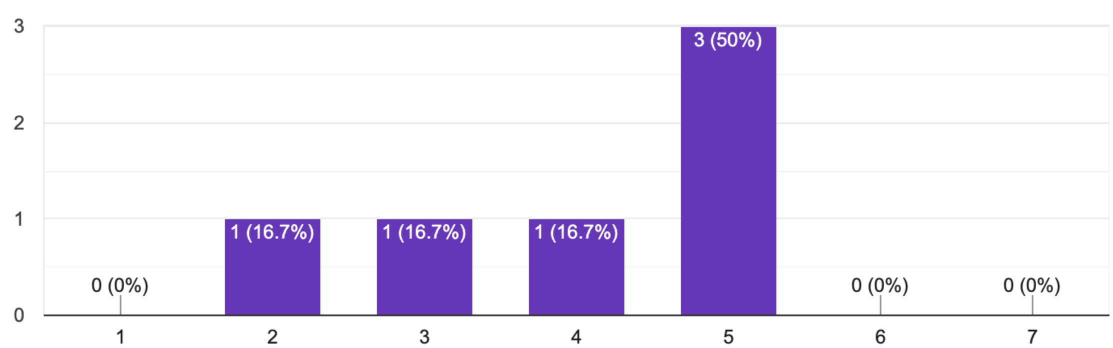
How many abdominal laparoscopic surgeries have you observed or participated in?

6 responses

-
>500
150 case range (>1300)
100
driven the camera, observed
600

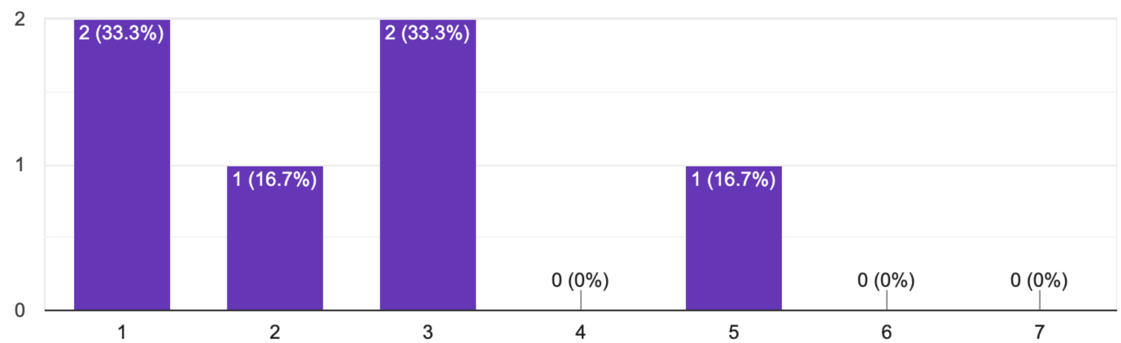
How visually realistic is model?

6 responses



Using the laparoscopic tools, do the organs feel similar to how it would in an operation setting?

6 responses



Write any comments about specific organs/tissues here (if any)

6 responses

Need to improve anatomic relations with structures that we have, stomach smaller, liver bigger, put inside of retroperitoneum, material needs to change, organs need to be attached a lot better to match anatomic relationships

too hard

good size, representation of actual person , needs to be softer

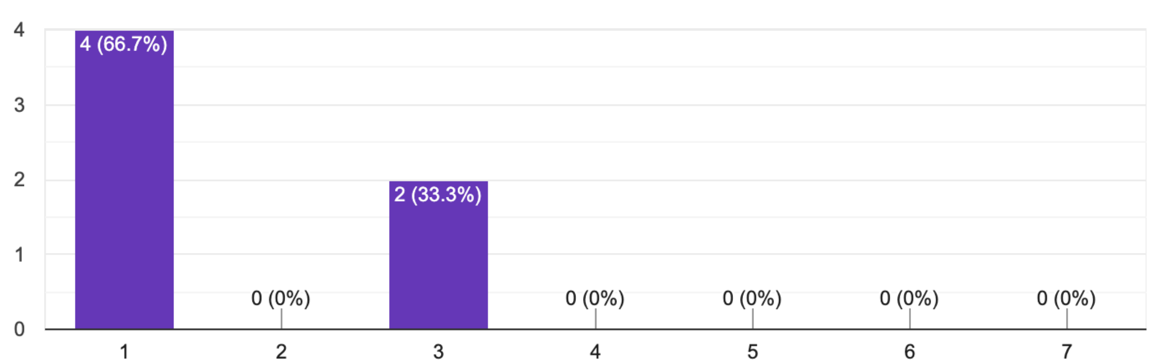
spatial relationships may not be proportional -

much better than current models in sim center; he's a med studet so can't answer the lapaoscopic questions accurately

visualization is most important in his opinion, there is more than the tissue and the retroperitoneum, it has a little harder feel than it should

Is the puncture strength/deformation of the model similar to human organs/tissues?

6 responses



Write any comments about specific organs/tissues here (if any)

6 responses

0 on all none of the organs should be very solid, mesentery is not anatomically correct in a way you can use it, glue needs to be better, membrane is good --- the membrane is perfect for membrane between the mesentery and colon. membrane would go all the way around the colon, membrane must be see through. Important -- the membrane material is a good materials (it would be good if it is less see through) but should be more see through and shrink wrapped to organs

cant poke through the organs (maybe represents a bad disease)

should be softer

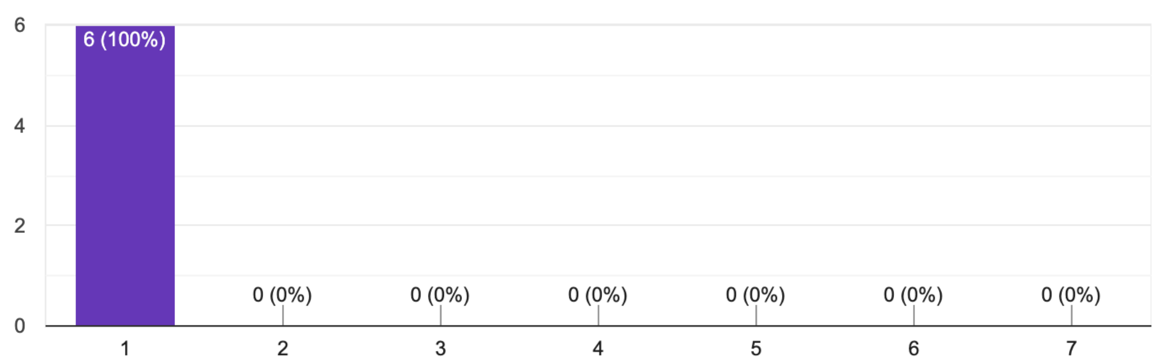
big strength - have organs in there where as the ones in the sim lab don't have organs you just use the pegs or cut circles etc. and the VR you don't get that tactile feedback

membrane feels most realistic, liver and intestine are too thick, everything else feels pretty good

colon not very, peritoneum is

Is the adhesive strength of the model similar to human organs/tissues?

6 responses



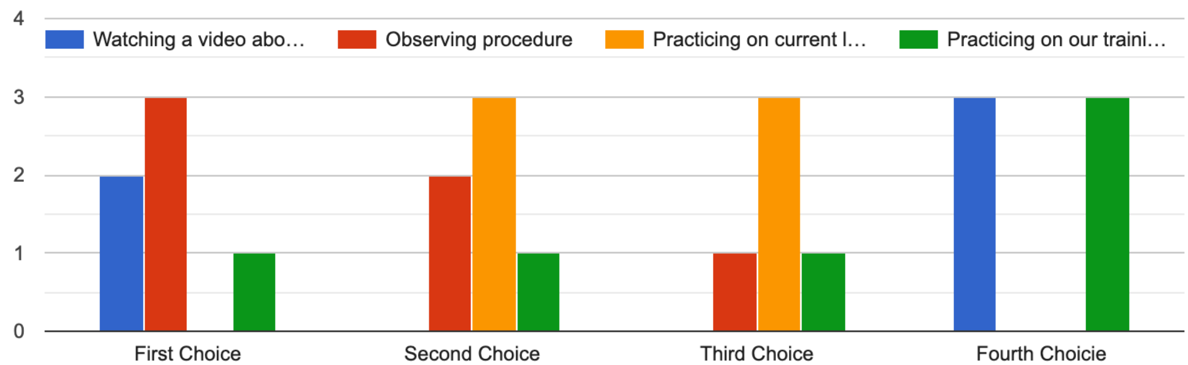
Write any comments about specific organs/tissues here (if any)

2 responses

everything is just too hard, need to be able to see through; kidney is probably closest to real

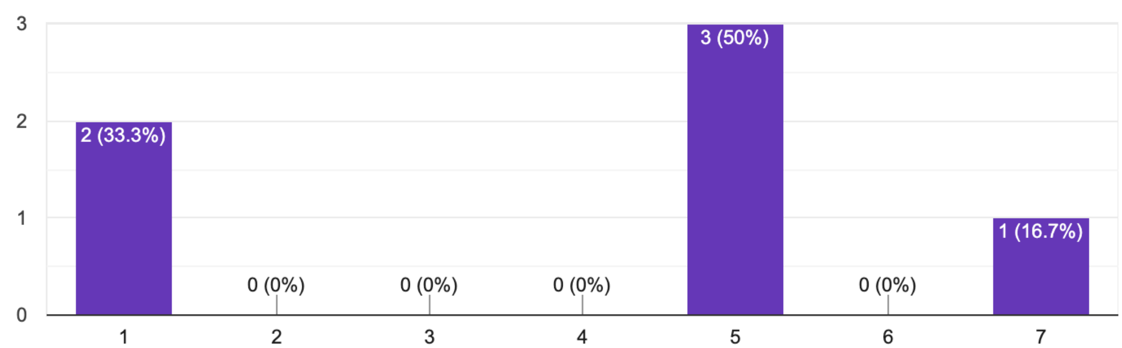
like the concept,

Rank the following from most to least useful for learning surgical skills



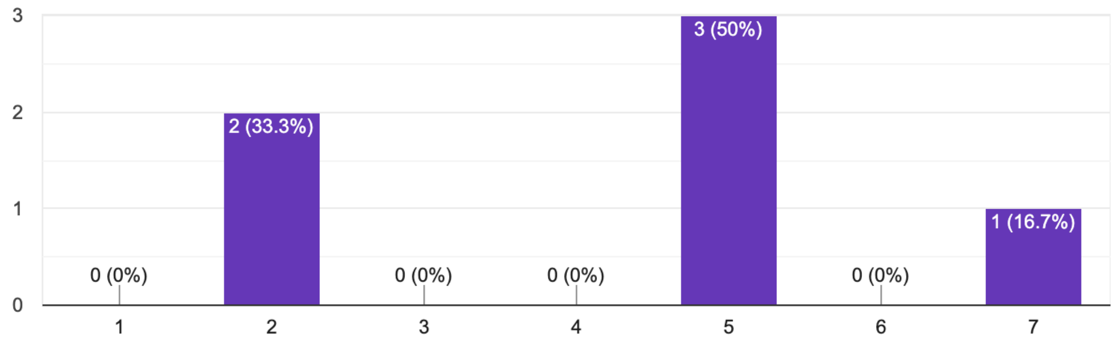
To what extent does experiencing the bio-realistic sensation through the model improve your understanding of what to expect in surgery?

6 responses



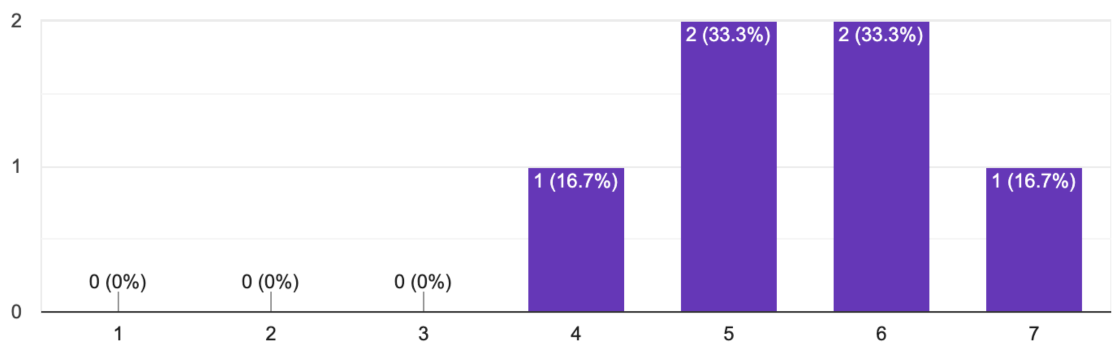
To what extent would you recommend this model as a learning tool to other medical students and residents?

6 responses



After playing around with the model for some time, did you find that it was easy to learn how to use?

6 responses



Any comments about ease of use should go here

2 responses

Easy to use, but not realistic. Not all tissues represented

Spatial relationships between structures are really important, but i have never done any kind of simulation that actually has tactile feedback before. This would be very helpful because you don't know how hard to push

Appendix M: Material Selection Analysis

P-value Calculations for Bovine and Synthetic Material Quantitative Test Results (highlighted: p>0.05)

PUNCTURE	Green Foam	Arts and Crafts Foam	Liquid Rubber	Oomoo	Parafilm	Saran Wrap	Stove Silicone	Sausage Casing (Dry)	Sausage Casing (Wet)	Ecoflex-20	Dragon-10	Dragon-20
Colon	0.0098619	0.00936836	0.32239039	0.09975176	0.00373906	0.000512052	0.92027485	0.094941105	0.00521066	0.06609255	0.97076346	0.29862476
Mesentary	0.01536054	0.012799	0.01111488	0.06965016	1.9232E-05	0.001872819	0.00039193	7.00689E-06	0.00490855	0.43305222	0.00073126	0.00068296
Small Intestine	0.00348171	0.00356758	0.02500429	0.01720339	0.0006205	0.002017536	0.09623579	0.089677886	0.01725504	0.06827687	0.11014329	0.84918708

PEEL	Double Side Tape	Nano Grip	Rubber Cement	Loctite Spray	Spirit	Hydrogel Patch	Hydrogel Collagen	Hydrogel Liquid	Gelatin-Glycerol	Ecoflex-20	Dragon-10	Dragon-20
Colon-Mesentary	0.13386552	0.1470226	0.12022894	0.11453835	0.11213965	0.144403366	0.11893136	0.115893159	0.11630022	0.19375465	0.02460818	0.02270785

TENSILE - UTS	Green Foam	Oomoo	PDMS
Colon	0.002111299	0.005323017	8.18149E-05
Mesentary	0.064586336	0.198541776	0.001905916
Small Intestine	0.001685853	0.218880271	0.001760951

TENSILE - TENSILE STRAIN	Green Foam	Arts and Crafts Foam	Oomoo	Parafilm	PDMS
Colon	3.61911E-05	0.087481009	0.029450778	0.481255195	0.55516699
Mesentary	0.000500162	0.113563993	0.376833659	0.521691077	0.14684108
Small Intestine	0.002188237	0.179651658	0.215631685	0.60178444	0.02181247

TENSILE - TANGENT MODULUS	Green Foam	Arts and Crafts Foam	Oomoo	PDMS
Colon	0.005999745	0.011282455	0.00812603	0.012422807
Mesentary	0.069681129	0.063728806	0.983428063	0.034064231
Small Intestine	0.037863431	0.965650242	0.21470204	0.740980821

TENSILE - LOAD TO FAILURE	Green Foam	Arts and Crafts Foam	Oomoo	Parafilm	PDMS	Sausage Casing	Saran Wrap	Stove Silicone
Colon	0.09073281	0.000789095	0.025712184	0.000481967	0.7452995	0.006263007	0.000313449	0.10931697
Mesentary	0.143349123	0.067697835	0.420283736	0.037722513	0.38394049	0.646420529	0.027112974	0.005953796
Small Intestine	0.101783546	0.138519714	0.299613272	0.031737267	0.3473161	0.927783262	0.014984623	0.002246034

TENSILE - COMPLIANCE	Green Foam	Arts and Crafts Foam	Oomoo	Parafilm	PDMS
Colon	0.017658763	0.035426716	0.007253877	0.074327099	0.00038018
Mesentary	0.011459362	0.204002401	0.309326964	0.053806131	0.19158128
Small Intestine	0.017523112	0.012195901	0.021252417	0.061354288	0.16320051

Significantly Equivalent Synthetic Materials from Tensile Test

Sample	Ultimate Tensile Strength (UTS)	Tensile Strain	Tangent Modulus	Load to Failure	Compliance
Colon	EcoFlex 00-30, 00-33 AF, and 00-20	Arts and Crafts Foam, Parafilm, PDMS	-	Green Foam, PDMS, Stove Silicone	Parafilm
Mesentery	Green Foam, Oomoo	Arts and Crafts Foam, Oomoo, Parafilm, PDMS	Arts and Crafts Foam, Oomoo	Green Foam, Arts and Crafts Foam, Oomoo, PDMS, Sausage Casing	Arts and Crafts Foam, Oomoo, Parafilm, PDMS
Small Intestine	Oomoo	Arts and Crafts Foam, Oomoo, Parafilm, PDMS	Arts and Crafts Foam, Oomoo, PDMS	Green Foam, Arts and Crafts Foam, Oomoo, PDMS, Sausage Casing	Parafilm, PDMS

Significantly Equivalent Synthetic Materials from Puncture Test

Sample	Puncture Force
Colon	Liquid Rubber, Oomoo, Stove, Sausage Casing, Ecoflex-20, Dragon-10, Dragon-20
Mesentery	Oomoo, Ecoflex-20
Small Intestine	Stove Silicone, Sausage Casing (Dry), Ecoflex-20, Dragon-10, Dragon-20

Significantly Equivalent Synthetic Materials from Peel Test

Sample	Peel Force
Colon-Mesentary	Double Side Tape, Nano Grip Tape, Rubber Cement, Loctite Spray, Spirit, Hydrogel Patch, Hydrogel Collagen, Hydrogel Liquid, Helatin-Glycerol, Ecoflex-20

Material Property Comparison of Bovine and Synthetic Quantitative Test Results

Sample	Avg UTS ± SD (MPa)	Avg Maximum Puncture Force ± SD (N/mm)	Average Peel Force ± SD (N/mm2)
Bovine Colon	1.81 ± 0.71	22.3 ± 7.1	-
Bovine Mesentery	0.34 ± 0.11	6.14 ± 1.86	-
Bovine Small Intestine	0.58 ± 0.19	26.5 ± 2.63	-
Kidney	-	12N (Gerwen)	-
Gallbladder	-	-	-
Liver	0.04	-	-
Stomach	0.5 to 0.7	4.2 ± 1.2 (cronin)	-
Bovine Colon - Mesentery	-	-	0.0029 ± 0.0018
Green Foam	0.12 ± 0.03	1.58 ± 0.23	-
Oomoo	0.46 ± 0.08	13.9 ± 2.3	-
PDMS	0.49 ± 0.25	238	-
Stove Silicone	-	21 ± 0.17	-
Saran Wrap	-	171.3 ± 13.2	-
Sausage Casing Dry	-	30.8 ± 0.91	-
Sausage Casing Wet		46.5 ± 6.09	-
Parafilm	-	46.6 ± 2.26	-
Arts and Crafts Foam	-	1.158 ± 0.031	-
Smooth-on: Eco-flex 5	2.41	-	-
Smooth-on: Eco-flex 00-50	2.17	13.07	-
Smooth-on: Eco-flex 00-30	1.38	9.6	-
Smooth-on: Eco-flex 00-33 AF	1.38	-	-
Smooth-on: Eco-flex 00-20	1.1	9.82 ± 4.36	-
Smooth-on: Eco-flex 00-10	0.83	-	-
Smooth-on: Dragon Skin 10 Very Fast	3.28	22.5 ± 1.23	-
Smooth-on: Dragon Skin 10 Fast	3.28	22.5 ± 1.23	-
Smooth-on: Dragon Skin 10 Medium	3.28	22.5 ± 1.23	-
Smooth-on: Dragon Skin 10 Slow	3.28	22.5 ± 1.23	-
Smooth-on: Dragon Skin 10 AF	3.28	22.5 ± 1.23	-
Smooth-on: Dragon Skin 20	3.79	26.8 ± 1.35	-
Smooth-on: Dragon Skin 30	3.45	37	-
Double-Sided Tape	-	-	3.2E-04 ± 9.7E-05
Nano Grip Tape	-	-	4.6E-04 ± 3.8E-05
Rubber Cement	-	-	3.2E-04 ± 9.7E-05
Loctite Spray	-	-	5.5E-05 ± 2.6E-05
Spirit Gum	-	-	1.8E-05 ± 4.1E-05
Hydrogel Patch	-	-	4.4E-04 ± 1.3E-04
Hydrogel Collagen Patch	-	-	1.2E-04 ± 9.8E-05
Gelatin - Glycerin	-	-	8.8E-05 ± 1.3E-04
Hydrogel Liquid	-	-	7.5E-05 ± 1.3E-05

Appendix N: Organ Molding Protocols

Stomach Mold Protocol

Goal: To fabricate a hollow stomach model out of a bio-realistic material.

Overview: 3D printed stomach models will be used to mold a stomach phantom out of silicone using a compression molding technique. This protocol will be used to fabricate a hollow organ that will eventually contain bodily fluids.

Materials:

- Smooth-On OOMOO™ 25 silicone
- (2) anatomically sized 3D printed stomach halves
- (2) 5% scaled down 3D printed stomach halves
- Plyers
- Sandpaper
- (2) mixing cups
- (2) wooden mixing stick
- Scalpel

Method:

1. Obtain a human STL model of the stomach and upload it to Blender®.
2. Slice the stomach model in half and export it as 2 STL files. Then, upload the stomach STL files to 3DPrinterOS® as G-code.
3. Scale the 2 stomach halves to the correct anatomical dimensions and 3D print them. Scale these files down 5% to obtain slightly scaled down stomach halves and print them. Remove the supports with plyers and use sandpaper to smooth the 3D models as needed.
4. Pour equal parts by volume of part A and B of the Smooth-On OOMOO™ 25 silicone in 2 mixing cups. Mix them together with a wooden mixing stick until homogenous. Use enough to coat the insides of the anatomically sized stomach halves.
5. Pour the silicone mixture into the 2 anatomically sized stomach halves. Place the 2 slightly scaled down stomach halves on top of the anatomically sized ones to compress the silicone.
6. Place weights on top of the 3D models until the silicone is compressed enough to coat the entire stomach.
7. Allow the molds to cure for at least 4 hours. They can be left overnight as well.
8. Once cured, gently remove the silicone molds from the 3D models. Put the silicone halves on top of one another and seal them together by applying another layer of Smooth-On OOMOO™ 25 silicone around the edges with another wooden mixing stick.

9. Put the mold in the anatomically sized stomach halves to hold the silicone mold in place and allow it to cure for at least 2 more hours or overnight.
10. Once cured, use the scalpel to cut off any extra silicone. Now, the final stomach mold is ready to be filled with bodily fluids, coated in glue, and placed in the box trainer.

Small Intestine Mold Protocol

Goal: To fabricate a hollow small intestine model out of a bio-realistic material.

Overview: A 3D printed intestine model will be used to mold a small intestine phantom out of silicone using inverse and compression molding techniques. This protocol will be used to fabricate a hollow organ that will eventually contain bodily fluids.

Materials:
- Smooth-On OOMOO™ 25 silicone
- (1) anatomically sized 3D printed small intestine segment
- (1) hollow cylinder 3D model
- Paraffin wax candle
- Stove
- Oven
- Oven mitt
- Pyrex® bowl
- Water
- Saucepan
- Freezer
- Plyers
- Sandpaper
- (2) mixing cups
- (2) wooden mixing stick
- 1 Liter graduated cylinder
- Scalpel

Method:
1. Obtain a human STL model of the intestines and upload it to Blender®.
2. Slice a section of the small intestines out of the intestine model and export it as an STL file. Then, upload the small intestine STL file to 3DPrinterOS® as G-code.
3. Scale the small intestine to the correct anatomical dimensions and 3D print them. Remove the supports with plyers and use sandpaper to smooth the 3D models as needed.
4. Design a hollow cylinder in a CAD software that follows the curvature of the small intestine model and has the internal diameter of a human small intestine (6.4 cm). Keep

one end of the hollow cylinder open and one end closed. Upload the file to 3DPrinterOS®
as G-code.

5. 3D print the hollow cylinder model. Remove the supports with plyers and use sandpaper to smooth the 3D model as needed.
6. Pour 1 L of water into a saucepan and heat the water on the stove on high (60 °C or higher) until the water comes to a boil.
7. Put the paraffin wax candle in a Pyrex® bowl and place it on the saucepan until the wax melts.
8. Using an oven mitt, pour the wax into the hollow cylinder model. Place the wax and 3D model in a freezer (-18 °C or below) upright until the wax mold is completely solidified.
9. Ply the hollow cylinder model off the solid wax with plyers until the wax can be removed from the model in one piece. Use a scalpel to smooth out the wax. Now the wax mold is ready to be used for the small intestine model. This can be stored in a cool area for as long as needed.
10. Pour equal parts by volume of alginate powder and water into 2 mixing cups. Mix them together with a wooden mixing stick and then pour it into a 1 L graduated cylinder deep enough to fit the small intestine 3D model.
11. Place the small intestine, vertically, in the alginate clay until it is immersed, while keeping the top of the model visible. Hold it in the clay and allow it to cure for 8 minutes to form an inverse organ mold. Once the alginate is fully cured, remove the 3D print to leave a hollow imprint of the organ half.
12. Pour equal parts by volume of part A and B of the Smooth-On OOMOO™ 25 silicone in 2 mixing cups. Mix them together with a wooden mixing stick until homogenous. Use enough to fill the inverse mold.
13. Pour the silicone mixture into the inverse mold in the alginate clay. Place the paraffin wax mold inside the inverse mold to compress the silicone around it.
14. Place weights on top of the wax mold until the silicone is compressed enough to coat the circumference of the inverse mold.
15. Allow the molds to cure for at least 4 hours. They can be left overnight as well.
16. Once cured, gently remove the silicone mold from the inverse model. Use the scalpel to cut off any extra silicone. Slice the silicone mold open at the ends with a scalpel if the mold if they are sealed shut.
17. Place the silicone mold in the Pyrex® bowl and put it in an oven set to 60 °C or higher to melt the wax out of the silicone mold.
18. Remove the bowl from the oven once the wax is completely melted out of the silicone. Now, the final small intestine mold is ready to be filled with bodily fluids, coated in glue, and placed in the box trainer.

Liver Mold Protocol

Goal: To fabricate a solid liver model out of a bio-realistic material.

Overview: 3D printed liver will be used to mold a liver phantom out of silicone using an inverse molding technique. This protocol will be used to fabricate a solid organ.

Note: We were unable to obtain mechanical properties for a human liver from literature or biological testing this year, so we used OOMOO™ 25 as a preliminary material so that we could still incorporate the liver in the anatomical display of the model.

Materials:
- Smooth-On OOMOO™ 25 silicone
- anatomically sized 3D printed liver
- Alginate Clay
- Water
- Plyers
- Sandpaper
- (4) mixing cups
- (3) wooden mixing sticks
- Glass container
- Scalpel

Method:
1. Obtain a human STL model of the liver and upload it to 3DPrinterOS® as G-code.
2. Scale the liver to the correct anatomical dimensions and 3D print it. Remove the supports with plyers and use sandpaper to smooth the 3D model as needed.
3. Pour equal parts by volume of alginate powder and water into 2 mixing cups. Mix them together with a wooden mixing stick and then pour it into a glass container large enough to fit the liver 3D model.
4. Place the liver on its side in the alginate clay until half of it is immersed. Hold it in the clay and allow it to cure for 8 minutes to form an inverse organ mold. Once the alginate is fully cured, remove the 3D print to leave a hollow imprint of the organ half.
5. Repeat this for the other half of the liver.
6. Pour equal parts by volume of part A and B of the Smooth-On OOMOO™ 25 silicone in 2 mixing cups. Mix them together with a wooden mixing stick until homogenous. Use enough to fill both inverse molds.
7. Pour the silicone mixture into the 2 inverse molds in the alginate clay and allow the molds to cure for at least 4 hours. They can be left overnight as well.

8. Once cured, gently remove the silicone molds from the inverse molds. Put the silicone halves on top of one another and seal them together by applying another layer of Smooth-On OOMOO™ 25 silicone on the base where they connect and around the edges with another wooden mixing stick. Allow it to cure for at least 2 more hours or overnight.
9. Once cured, use the scalpel to cut off any extra silicone. Now, the final liver mold is ready to be coated in glue and placed in the box trainer.

Right Kidney Mold Protocol

Goal: To fabricate a solid right kidney model out of a bio-realistic material.

Overview: 3D printed right kidney molds will be used to mold a right kidney phantom out of silicone using an inverse molding technique. This protocol will be used to fabricate a solid organ.

Materials:

- Smooth-On Dragon Skin™ Series 10 silicone
- (2) anatomically sized 3D printed right kidney halves
- Alginate Clay
- Water
- Plyers
- Sandpaper
- (4) mixing cups
- (3) wooden mixing sticks
- Glass container
- Scalpel

Method:

1. Obtain a human STL model of the kidney and upload it to Blender®.
2. Slice the kidney model in half and export it as 2 STL files. Then, upload the kidney STL files to 3DPrinterOS® as G-code.
3. Scale the kidney to the correct anatomical dimensions and 3D print it. Remove the supports with plyers and use sandpaper to smooth the 3D model as needed.
4. Pour equal parts by volume of alginate powder and water into 2 mixing cups. Mix them together with a wooden mixing stick and then pour it into a glass container large enough to fit the kidney 3D model.
5. Place the kidney on its side (exterior face down) in the alginate clay until its exterior face is immersed. Hold it in the clay and allow it to cure for 8 minutes to form an inverse organ mold. Once the alginate is fully cured, remove the 3D print to leave a hollow imprint of the organ half.

6. Repeat this for the other half of the kidney.
7. Pour equal parts by volume of part A and B of the Smooth-On Dragon Skin™ Series 10 silicone in 2 mixing cups. Mix them together with a wooden mixing stick until homogenous. Use enough to fill both inverse molds.
8. Pour the silicone mixture into the 2 inverse molds in the alginate clay and allow the molds to cure for at least 4 hours. They can be left overnight as well.
9. Once cured, gently remove the silicone molds from the inverse molds. Put the silicone halves on top of one another and seal them together by applying another layer of Smooth-On Dragon Skin™ Series 10 silicone on the base where they connect and around the edges with another wooden mixing stick. Allow it to cure for at least 2 more hours or overnight.
10. Once cured, use the scalpel to cut off any extra silicone. Now, the final kidney mold is ready to be coated in glue and placed in the box trainer.

Gallbladder Mold Protocol

Goal: To fabricate a hollow gallbladder model out of a bio-realistic material.

Overview: A 3D printed gallbladder will be used to mold a gallbladder phantom out of silicone using an inverse and compression molding techniques. This protocol will be used to fabricate a hollow organ.

Materials:

- Smooth-On Dragon Skin™ Series 20 silicone
- anatomically sized 3D printed gallbladder
- Alginate Clay
- Water
- Plyers
- Sandpaper
- (4) mixing cups
- (3) wooden mixing sticks
- Glass container
- Scalpel

Method:

1. Obtain a human STL model of the gallbladder and upload it to 3DPrinterOS® as G-code.

2. Scale the gallbladder to the correct anatomical dimensions and 3D print them. Remove the supports with plyers and use sandpaper to smooth the 3D models as needed.
3. Pour equal parts by volume of alginate powder and water into 2 mixing cups. Mix them together with a wooden mixing stick and then pour it into a glass container large enough to fit the gallbladder 3D model.
4. Place the gallbladder on its side in the alginate clay until half of it is immersed. Hold it in the clay and allow it to cure for 8 minutes to form an inverse organ mold. Once the alginate is fully cured, remove the 3D print to leave a hollow imprint of the organ half.
5. Pour equal parts by volume of part A and B of the Smooth-On Dragon Skin™ Series 20 silicone in 2 mixing cups. Mix them together with a wooden mixing stick until homogenous. Use enough to fill 2 inverse molds.
6. Pour the silicone mixture into the inverse mold. Place the gallbladder model on top of the inverse mold to compress the silicone.
7. Place weights on top of the 3D models until the silicone is compressed enough to coat half of the model
8. Repeat this for the other half of the gallbladder.
9. Allow the molds to cure for at least 4 hours. They can be left overnight as well.
10. Once cured, gently remove the silicone molds from the inverse molds. Put the silicone halves on top of one another and seal them together by applying another layer of Smooth-On Dragon Skin™ Series 20 silicone around the edges with another wooden mixing stick. Allow it to cure for at least 2 more hours or overnight.
11. Once cured, use the scalpel to cut off any extra silicone. Now, the final gallbladder mold is ready to be filled with bodily fluids, coated in glue, and placed in the box trainer.

Mesentery Mold Protocol

Goal: To fabricate the mesentery tissue out of a bio-realistic material.

Overview: This protocol will be used to fabricate a layer of mesentery tissue that can be folded and anatomically arranged in the model.

Materials:

- Smooth-On OOMOO™ 25 silicone
- 28 cm x 28 cm x 4 cm container
- Plyers
- Sandpaper
- (2) mixing cups
- (2) wooden mixing sticks
- Scalpel

Method:

1. Obtain a container with at least the dimensions of 28 cm x 28 cm x 4 cm. The bottom of a plastic container can also be used.
2. Pour equal parts by volume of part A and B of the Smooth-On OOMOO™ 25 silicone in 2 mixing cups. Mix them together with a wooden mixing stick until homogenous. Use enough to fill the base of the container.
3. Pour the silicone mixture into the container. Do not allow the silicone to exceed a height of 0.3cm.
4. Allow the mold to cure for at least 4 hours. It can be left overnight as well.
5. Once cured, gently remove the silicone mold from the container. Use the scalpel to cut the silicone into the desired fan shape of the mesentery. Now, the final mesentery mold is ready to be coated in glue and placed in the box trainer.

Retroperitoneum Mold Protocol

Goal: To fabricate the retroperitoneum by making a slime-like material

Overview: This protocol will be used to fabricate slime that will serve as the retroperitoneum in the model.

Materials:

- 4 ounces Elmer's ® Glue
- 4 ounces Warm Water
- 4 ounces Warm Water
- 1 Teaspoon Borax powder
- (2) mixing cups

Method:

1. Pour 118mL (4 ounces) of glue and 118mL (4 ounces) of warm water into the mixing cup. Start mixing this solution.
2. In the second mixing cup, mix 5mL (1 teaspoon) of borax powder and 118mL (4 ounces) warm water together.
3. Add the borax solution to the mixing cup with the glue solution.
4. Stir the final solution together, and the slime should form.
5. Store the slime in a sealed container.

Note: This protocol will only produce a small sample of slime. Material amounts will have to be increased for a larger yield

Appendix O: Bill of Materials in Final Design

Here is the breakdown of the materials and costs of materials used in the final prototype of the surgical phantom. The Smooth-On Silicone total cost was the estimated cost to fabricate 6 organs: the liver, small intestine, mesentery, right kidney, mesentery, and stomach. Because we used different types of silicones, we estimated that in total we used two full kits of silicone, which were all marketed at a price of $32.21, totaling to $64.42 to fabricate these six organs for the model. The McMaster Carr® Sheet was used as the retroperitoneum in our model. In future iterations, the model should incorporate more of this material, as it should wrap around all of the organs, whereas in this iteration, there was only enough to wrap around the colon. The box trainer was fabricated using OPTIX® clear cast, paper-masked acrylic sheets ($28.00), Gorilla® Super Glue Gel ($11.94), Master Magnetics® Flexible Tape Roll ($5.97), 3M® 799198554562 10' X 1" Black Scotch Extreme Fasteners ($14.98), Con-Tact® Simple Elegance Clear Diamond Shelf/Drawer Liner ($9.98), and Plast-O-Mat® Black Ribbed Shelf Liner ($13.67). Individual units of the aforementioned items were purchased, though not all the material was used; therefore, the $45 price of the box trainer is an estimate based on the actual quantity of material used.

Material	**Unit Price**	**Quantity per Model**	**Price**
Smooth-On Silicone (Organ Fabrication)	$32.21	2	$64.42
Colon (Stratasys® 3D Manufacturing)	$578	1	$578.00
McMaster Carr® Sheet (High Temperature Silicone Rubber Sheet, Ultra-Thin 10A Durometer)	$30.70	1	$30.70
Elmer's Foam Boards	$2.05	1	$2.05
Box Trainer	$45.00	1	$45.00
Loctite Spray	$6.99 (estimate)	1	$6.99 (estimate)
Retroperitoneum Fabrication	$1.31	5	$6.55 (estimate)
Total			**$733.71**

Appendix P: Beth Israel Final Model Survey

Survey Questions

BI Final Model Survey

Please fill out the survey. Thank you so much for helping our team out. We really appreciate it!

* Required

1. Year of Residency *

2. Area/Specialization *

3. What forms of laparoscopic training have you received? *

4. How many abdominal laparoscopic surgeries have you observed or participated in? *

Questions about Bio-realistic Properties of Model

5. How visually realistic is model? *

Mark only one oval.

	1	2	3	4	5	6	7	
Least realistic	◯	◯	◯	◯	◯	◯	◯	Most realistic

6. Using the laparoscopic tools, do the organs feel similar to how it would in an operation setting? *

Mark only one oval.

	1	2	3	4	5	6	7	
Not similar	⬭	⬭	⬭	⬭	⬭	⬭	⬭	Very similar

7. Write any comments about specific organs/tissues here (if any)

____

8. Is the puncture strength/deformation of the model similar to human organs/tissues? *

Mark only one oval.

	1	2	3	4	5	6	7	
Not similar	⬭	⬭	⬭	⬭	⬭	⬭	⬭	Very similar

9. Write any comments about specific organs/tissues here (if any)

10. Is the adhesive strength of the model similar to human organs/tissues? *

Mark only one oval.

	1	2	3	4	5	6	7	
Not similar	⬭	⬭	⬭	⬭	⬭	⬭	⬭	Very similar

11. Write any comments about specific organs/tissues here (if any)

12.

Mark only one oval.

- Option 1

Questions about Educational Properties of Model

13. Rank the following from most to least useful for learning surgical skills *

Mark only one oval per row.

	Watching a video about procedure	Observing procedure	Practicing on current laparoscopic trainers	Practicing on our training model
First Choice				
Second Choice				
Third Choice				
Fourth Choicie				

14. To what extent does experiencing the bio-realistic sensation through the model improve your understanding of what to expect in surgery? *

Mark only one oval.

	1	2	3	4	5	6	7	
Improves understanding a little								Improves understanding a lot

15. To what extent would you recommend this model as a learning tool to other medical students and residents? *

Mark only one oval.

	1	2	3	4	5	6	7	
Would not reccomend	⬭	⬭	⬭	⬭	⬭	⬭	⬭	Would highly reccomend

Questions about Ease of Use Properties of Model

16. After playing around with the model for some time, did you find that it was easy to learn how to use? *

Mark only one oval.

	1	2	3	4	5	6	7	
Very hard	⬭	⬭	⬭	⬭	⬭	⬭	⬭	Very easy

17. Any comments about ease of use should go here

____

Survey Responses

Year of Residency

6 responses

- Not Resident (Doctor)
- Attending
- 5th year
- 1st year
- medical student
- 5

Area/Specialization

6 responses

- Colorectal
- Colorectal Surgery
- cardiac (general surgery resident)
- general resident
- not sure
- surgical oncology

What forms of laparoscopic training have you received?

6 responses

-

box trainer, cadaver, simulator, intraoperative

in the OR, sim center -- box trainers

sim center - , some stuff at transplant peritoneal catheters, mostly driving camera

one sim session a year ago

OR cases, Simlab laparoscopic FLS course and robotic stuff

How many abdominal laparoscopic surgeries have you observed or participated in?

6 responses

-

>500

150 case range (>1300)

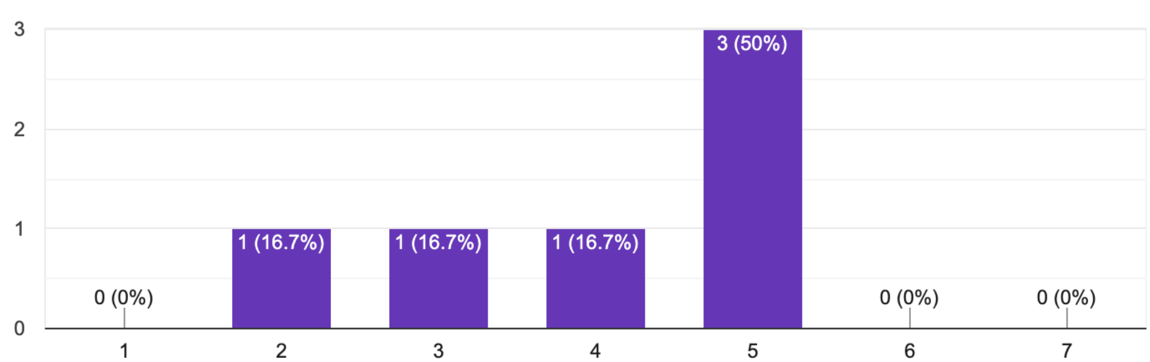
100

driven the camera, observed

600

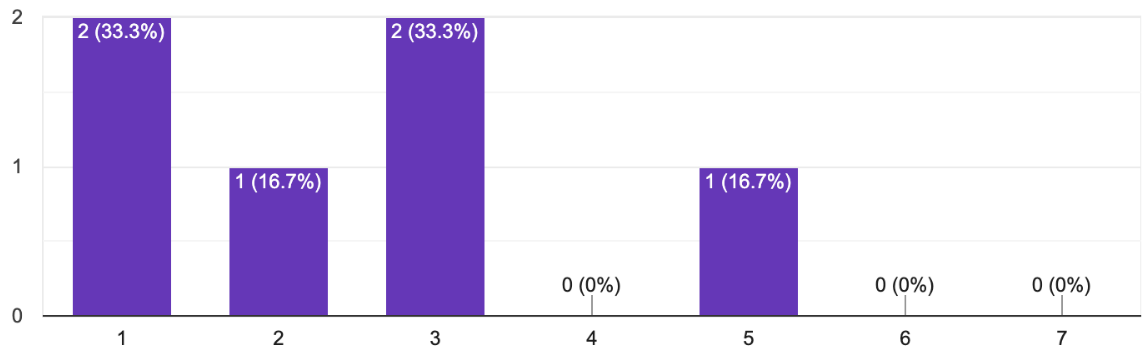
How visually realistic is model?

6 responses



Using the laparoscopic tools, do the organs feel similar to how it would in an operation setting?

6 responses



Write any comments about specific organs/tissues here (if any)

6 responses

Need to improve anatomic relations with structures that we have, stomach smaller, liver bigger, put inside of retroperitoneum, material needs to change, organs need to be attached a lot better to match anatomic relationships

too hard

good size, representation of actual person , needs to be softer

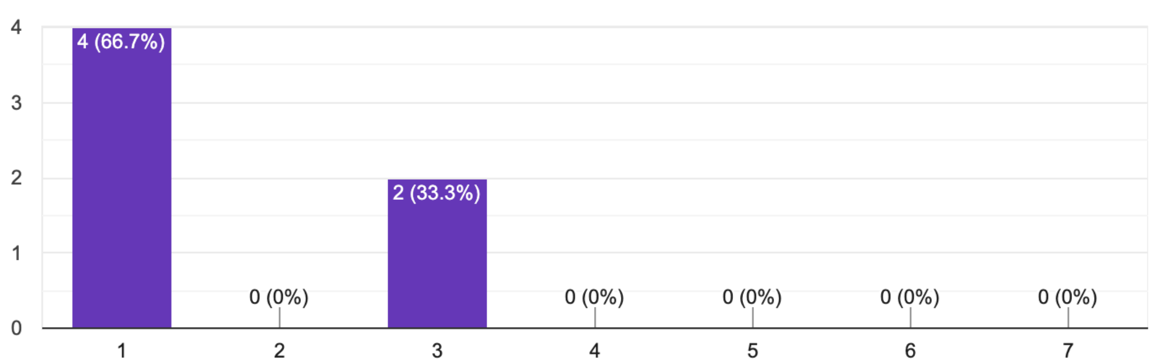
spatial relationships may not be proportional -

much better than current models in sim center; he's a med studet so can't answer the lapaoscopic questions accurately

visualization is most important in his opinion, there is more than the tissue and the retroperitoneum, it has a little harder feel than it should

Is the puncture strength/deformation of the model similar to human organs/tissues?

6 responses



Write any comments about specific organs/tissues here (if any)

6 responses

0 on all none of the organs should be very solid, mesentery is not anatomically correct in a way you can use it, glue needs to be better, membrane is good --- the membrane is perfect for membrane between the mesentery and colon. membrane would go all the way around the colon, membrane must be see through. Important -- the membrane material is a good materials (it would be good if it is less see through) but should be more see through and shrink wrapped to organs

cant poke through the organs (maybe represents a bad disease)

should be softer

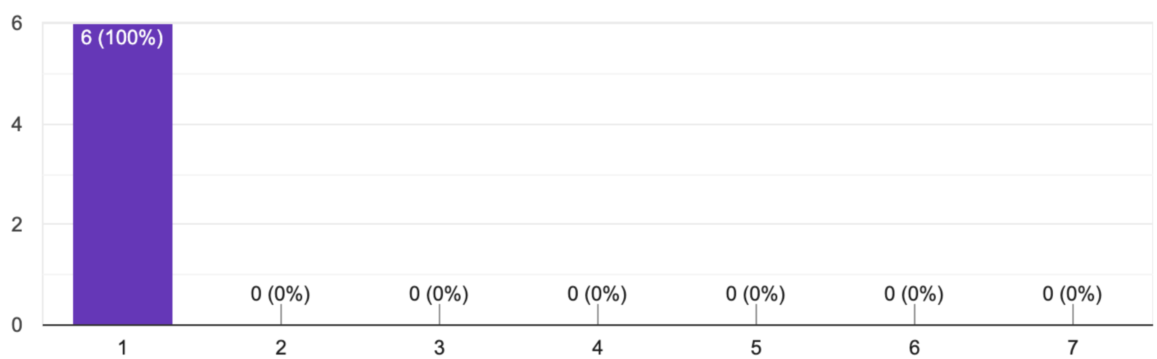
big strength - have organs in there where as the ones in the sim lab don't have organs you just use the pegs or cut circles etc. and the VR you don't get that tactile feedback

membrane feels most realistic, liver and intestine are too thick, everything else feels pretty good

colon not very, peritoneum is

Is the adhesive strength of the model similar to human organs/tissues?

6 responses



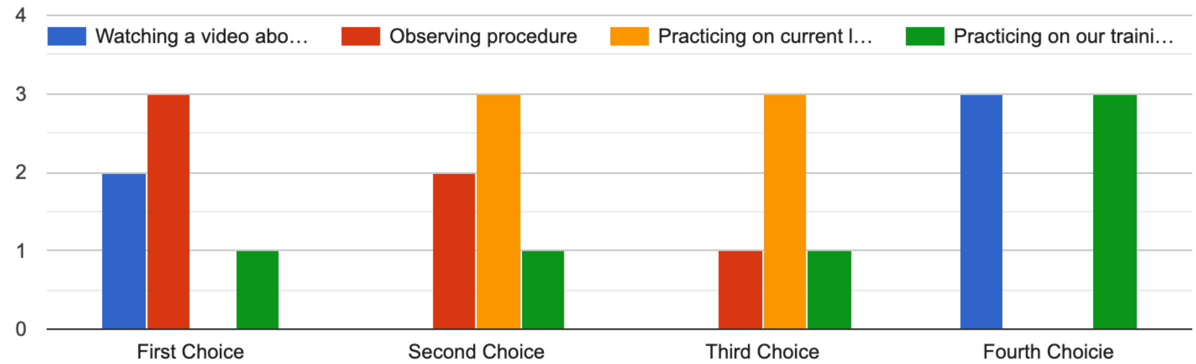
Write any comments about specific organs/tissues here (if any)

2 responses

everything is just too hard, need to be able to see through; kidney is probably closest to real

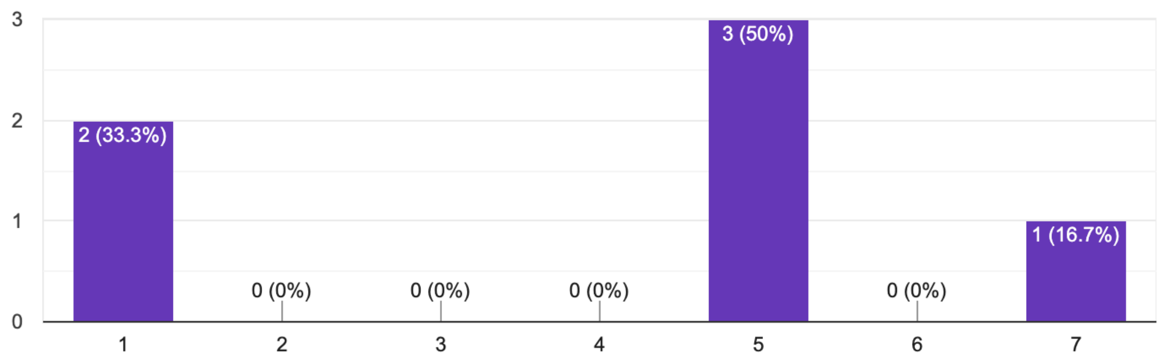
like the concept,

Rank the following from most to least useful for learning surgical skills



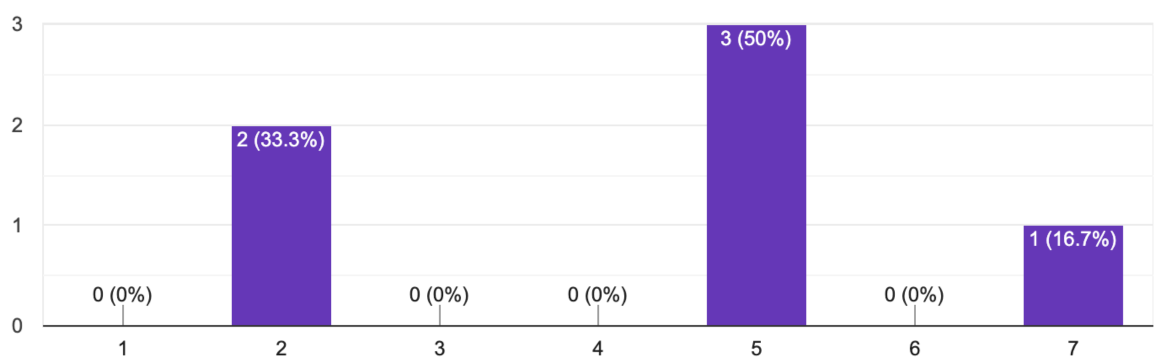
To what extent does experiencing the bio-realistic sensation through the model improve your understanding of what to expect in surgery?

6 responses



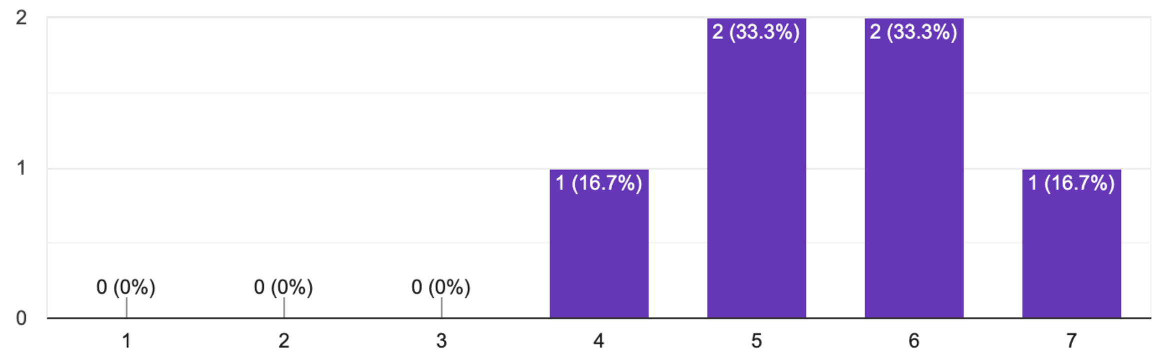
To what extent would you recommend this model as a learning tool to other medical students and residents?

6 responses



After playing around with the model for some time, did you find that it was easy to learn how to use?

6 responses



Any comments about ease of use should go here

2 responses

Easy to use, but not realistic. Not all tissues represented

Spatial relationships between structures are really important, but i have never done any kind of simulation that actually has tactile feedback before. This would be very helpful because you don't know how hard to push